Nos. 2023-2397, -2398
Volume I of III, Appx1 to Appx3506

In the United States Court of Appeals for the Federal Circuit

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,

Appellant,

v.

OSTEOMED LLC,

Appellee.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2022-00487 and IPR2022-00488.

CORRECTED JOINT APPENDIX

DEVON C. BEANE
JASON A. ENGEL
JONAH B. HEEMSTRA
K&L GATES LLP
70 West Madison Street
Suite 3100
Chicago, Illinois 60602-4207
(312) 807-4436
devon.beane@klgates.com
jason.engel@klgates.com
Jonah.Heemstra@klgates.com

SHARON A. HWANG
ROBERT A. SURRETTE
SCOTT P. MCBRIDE
SEAN C. SPARROW
McANDREWS, HELD & MALLOY, LTD.
500 West Madison Street, 34th Floor
Chicago, Illinois 60661
(312) 775-8000
shwang@mcandrews-ip.com
bsurrette@mcandrews-ip.com
smcbride@mcandrews-ip.com
ssparrow@mcandrews-ip.com

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Trials@uspto.gov
571-272-7822

Paper 37
Date: August 4, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00487
Patent 9,078,713 B2

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

OsteoMed LLC ("Petitioner") filed a Petition (Paper 1, "Pet."), seeking *inter partes* review of claims 32–39 of U.S. Patent No. 9,078,713 B2 (Ex. 1001, "the '713 patent"). We instituted trial on all grounds in the Petition. Paper 8, 34.

Following institution, Stryker European Operations Holdings LLC ("Patent Owner") filed a Response (Paper 16, "Resp."), Petitioner filed a Reply (Paper 25, "Reply"), and Patent Owner filed a Sur-reply (Paper 31, "Sur-reply"). We held a hearing on May 11, 2023, and a transcript is of record. Paper 36 ("Tr.").

After considering the parties' arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that the challenged claims of the '713 patent are unpatentable. *See* 35 U.S.C. § 316(e). Our reasoning is explained below.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies OsteoMed LLC, Acumed LLC, and Colson Medical, LLC as real parties in interest. *See* Pet. ix. Petitioner additionally identifies Marmon Holdings, Inc. and Berkshire Hathaway Inc. as "parties that may be relevant to the determinations." *Id.* Patent Owner identifies Stryker European Operations Holding LLC, Stryker Corporation, and Howmedica Osteonics Corp. *See* Paper 14, 2.

B. Related Matters

Petitioner and Patent Owner identify *OsteoMed LLC v. Stryker Corporation*, 1:20-cv-06821 (N.D. Ill.) as a related matter. Pet. x; Paper 5,

2–3. Patent Owner additionally identifies *OsteoMed LLC v. Wright Medical Technology, Inc.*, 1:20-cv-01621 (D. Del.). Paper 14, 3.

Petitioner also identifies IPR2022-00486 and IPR2022-00488, which were filed concurrently with the Petition and involve the same parties. Pet. x. We denied institution in IPR2022-00486. *See* IPR2022-00486, Papers 8, 12. IPR2022-00488 is currently pending.

C. The '713 Patent

The '713 patent issued on July 14, 2015, and is a continuation of an application filed on October 2, 2009. Ex. 1001, code (63).

The '713 patent relates to "a plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of said plate" that is configured to bring "the two bone parts into a compressive position." Ex. 1001, code (57). Figure 3 of the '713 patent provides a perspective view of this plate and is reproduced below.

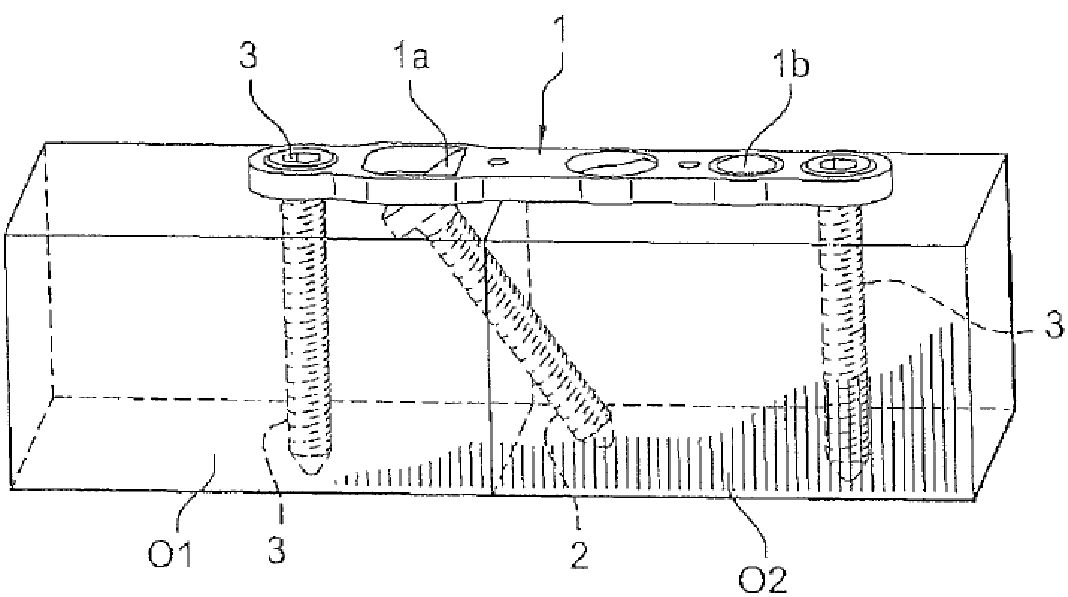

Fig. 3

Figure 3 depicts a plate 1 positioned between two bone parts O1 and O2. Ex. 1001, 2:16–17. Screws 3 are set through holes in the plate to attach it to bone parts O1 and O2. *Id.* at 2:33–35. A third screw 2 is positioned at an angle through a hole in tab 1a such that it extends through both parts O1 and O2. *Id.* at 1:64–66, 2:28–29. According to the Specification, engaging screw 2 in this manner "place[s] the fracture in compression." *Id.* at 2:28–29.

D. Challenged Claims

The Petition challenges claims 32–39. Claim 32 is the only independent claim and illustrative. Claim 32 is reproduced below with the same bracketed annotations used in the Petition to identify particular limitations.

> 32. [32Pre] A method of fusing a joint, the method comprising:
>
> [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;
>
> [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;
>
> [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and
>
> [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and [32e] a head of the third fixation member is seated in the third hole, [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate, [32g] wherein the third fixation member is the only fixation member extending across the joint.

Ex. 1001, 5:1–19.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
32, 33, 36, 37	103(a)	Slater[2]
34, 35, 39	103(a)	Slater, Myerson[3]
32, 33, 38	103(a)	Slater, Zahiri[4]
32, 33, 36–39	103(a)	Arnould,[5] Zahiri
34, 35	103(a)	Arnould, Zahiri, Myerson

In support of these grounds, Petitioner relies on the declaration of Michael Sherman (Ex. 1002) submitted with the Petition. Patent Owner relies on declarations from Karl R. Leinsing (Ex. 2005) and George B. Holmes (Ex. 2007) submitted with the Patent Owner Response.

Our analysis below focuses on Grounds 4 and 5, i.e., the two grounds relying on Arnould instead of Slater. Grounds 4 and 5 collectively reach all of the challenged claims.

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[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. § 103 that became effective after the filing of the applications to which the '713 patent claims priority. Therefore, we apply the pre-AIA version of § 103.
[2] WO 2007/131287 A1, published November 22, 2007 (Ex. 1004) ("Slater").
[3] US2006/0241608 A1, published October 26, 2006 (Ex. 1008) ("Myerson")
[4] US 8,187,276 B1, filed September 26, 2006 and issued May 29, 2012 (Ex. 1007) ("Zahiri").
[5] EP 1,897,509 B1, published December 3, 2008 (Ex. 1005). Exhibit 1006 is a certified translation of EP 1,897,509 B1, which we cite and refer to herein as "Arnould."

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Subsumed within the *Graham* factors is the requirement that the skilled artisan would have had a reasonable expectation of success in combining the prior art references to achieve the claimed invention. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). "Obviousness does not require absolute predictability of success . . . . [A]ll that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988). Moreover, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416.

On the other hand, a patent claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. An obviousness determination requires finding "both 'that a skilled artisan would have been motivated to combine

the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted).

B. Level of Ordinary Skill in the Art

Relying on the testimony of its declarant, Mr. Sherman, Petitioner contends that a person of ordinary skill in the art (POSITA) of the '713 patent

> as of October of 2009, had, among other attributes, a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and had approximately three years of experience with orthopedic implant design. Such a POSITA would have had knowledge of design considerations known in the industry and would have been familiar with then-existing products and solutions. A POSITA would have been familiar with orthopedic implants, bone plates, and intramedullary implants.

Pet. 6 (citing Ex. 1002 ¶¶ 55–57).

In its Response, Patent Owner argues that

> [i]n pending IPRs involving Petitioner's own patents relating to the same bone plate technology, the parties and the Board agreed that "a POSITA at the time of the invention would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon."

Resp. 10. Patent Owner urges that same level of ordinary skill in the art should apply here. *Id.* at 11.

Patent Owner disagrees with Petitioner's proposal to the extent it "excludes clinical practitioners with a medical degree and at least two years of experience as an orthopedic surgeon." Resp. 11 (internal quotations omitted). Patent Owner argues that "Petitioner's omission of clinical practitioners from its definition appears to be an oversight because Petitioner's expert . . . agreed at his deposition that orthopedic surgeons should be included within the definition of a POSITA." *Id.* (citing Ex. 2009, 38:21–39:17).

Petitioner did not respond to Patent Owner's argument regarding the level of ordinary skill in the art in its Reply and confirmed at the hearing that it does not dispute Patent Owner's proposed description. *See* Tr. 62:3–16.

While both parties' descriptions are similar, we find that Patent Owner's description is better supported by the record. As Patent Owner points out, the main distinction between the parties' proposals is that Patent Owner's description is broader because it includes orthopedic surgeons. The record supports the inclusion of such individuals in the description of a POSITA. *See* Ex. 2005 ¶¶ 37, 41; Ex. 2009, 38:21–39:7 (Petitioner's declarant testifying that he would "include an orthopedic surgeon that has some experience developing implants as a person of ordinary skill in the art"). Thus, we apply Patent Owner's description of a POSITA for our analysis.

C. Claim Construction

Patent Owner argues that we should construe the term "bone plate." Resp. 12–13. More specifically, Patent Owner argues that "[b]ecause Petitioner fails to define the term 'bone plate,' Petitioner's obviousness

analysis relies on nonanalogous art, such as Zahiri." *Id.* at 12. Patent Owner alleges that the '713 patent "defines 'bone plate' as 'a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts.'" *Id.* at 12–13 (quoting Ex. 1001, 1:20–22). Patent Owner contrasts this with the device disclosed in Zahiri, which "is designed to be positioned on only one side of a fracture – [such that] it does not span any fracture, let alone a joint." *See id.* at 36 (urging that Zahiri "does ***not*** disclose a 'bone plate,' as properly defined"). According to Patent Owner, we can "resolve the controversy regarding the meaning of 'bone plate" by "determin[ing] that the claim term 'bone plate' refers to a 'a plate adapted to be fixed ***between two bone parts*** to immobilize a fracture or joint.'" *Id.* at 13.

Petitioner generally disputes Patent Owner's position, urging that the Specification does not define the term differently than its plain and ordinary meaning. Reply. 3. According to Petitioner, none of the "dictionary definitions [Patent Owner cites] require the plate itself cross a fracture or joint to be fixed." *Id.* at 4 (citing Ex. 2012, 5; Ex. 2013, 4). Moreover, Petitioner points to Mr. Sherman's testimony and other evidence that bone plates for fracture fixation are "not always" placed across the fracture. *Id.* (citing Ex. 2009, 52:9–53:1; Ex. 1019). Accordingly, Petitioner contends that "to the extent 'bone plate' requires explicit construction . . . it must include plates that are positioned on one side of a joint or fracture consistent with the term's plain and ordinary meaning." *Id.*

We begin by observing that Patent Owner does not dispute that both Arnould and Slater disclose a "bone plate" regardless of how the term is construed. *See* Tr. 41:1–6. Rather, Patent Owner seeks to construe "bone plate" to further its attempt to show that Zahiri is not analogous art, and

therefore, cannot be combined with the other references. As explained below, we find that Zahiri is analogous art even if we were to adopt Patent Owner's proposal limiting "bone plate" to a plate "adapted to be fixed between two parts to immobilize a fracture or joint" because it is in the same field of endeavor, i.e., orthopedic implants, as the '713 patent. *Infra* § III.E.i.

That said, we do not agree with Patent Owner that the Specification defines "bone plate" as it contends. In the background of the invention, the Specification states that "[t]he invention relates to the technical field of orthopedic implants. More particularly, the invention relates to a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts." Ex. 1001, 1:18–22. Contrary to Patent Owner's argument, this passage does not "define" the term "bone plate" nor otherwise suggest that the patentee acted as its own lexicographer. *See* Resp. 12–13.

Moreover, nothing in the record suggests that the ordinary meaning of "bone plate" requires the plate to be fixed between two bone parts. The medical dictionaries Patent Owner cites do not include such a requirement in their definitions. *See* Ex. 2012, 1478 (defining "bone plate" as "a metal bar with perforations for the insertion of screws, used to immobilize fractured segments"); Ex. 2013, 241 (defining "bone plate" as "a metal plate used to reconstruct a bone that has been fractured" and "designed to hold the bone fragments in apposition"). Both of these definitions are consistent with Mr. Sherman's testimony that a bone plate is "not always" placed across the fracture. *See* Ex. 2009, 52:9–53:1 (identifying particular instances in which a plate is not placed across the fracture). We credit that testimony over the competing testimony of Patent Owner's declarant, Mr. Leinsing. Ex. 2005

¶ 33 (referring to the statement from the Specification and dictionary definitions discussed above).

For these reasons, we agree with Petitioner that the term "bone plate" as recited in the challenged claims has its ordinary meaning and that meaning does not exclude plates located on only one side of a joint or fracture. To the extent any further claim construction is necessary to resolve the issues presented in this proceeding, we consider such in our analysis below.

D. Overview of Arnould, Zah

i. Arnould

Arnould is a European patent filed September 10, 2007 and published on March 12, 2008. Ex. 1006, codes (22), (43). Petitioner asserts, and Patent Owner does not dispute, that Arnould qualifies as prior art under 35 U.S.C. § 102(b). Pet. 9.

Arnould describes "an arthrodesis plate for a metatarsal-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe" and "a surgical method for placing such an arthrodesis plate." Ex. 1006 ¶ 1.

Figure 1 of Arnould, reproduced below, "depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." Ex. 1006 ¶ 11.

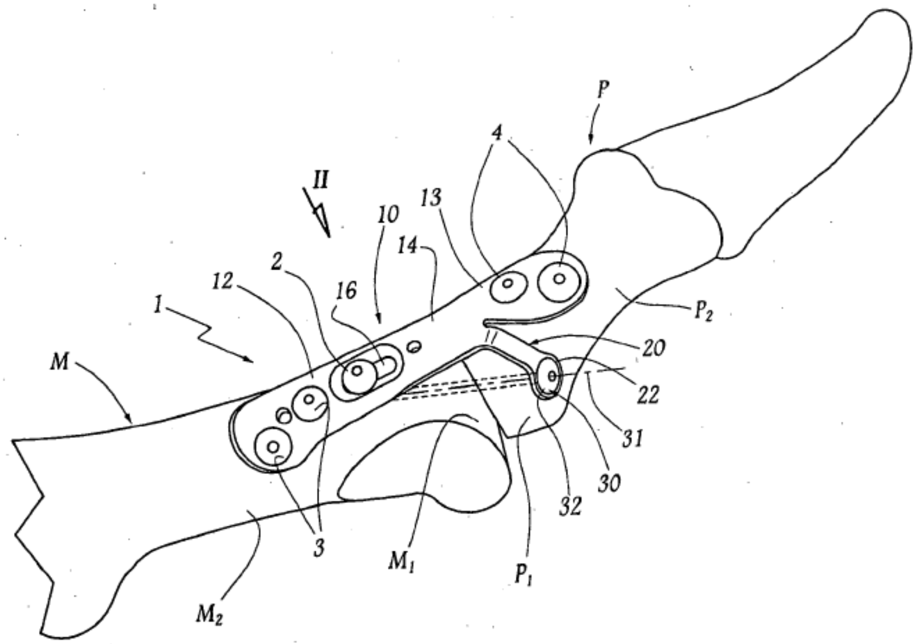

Fig.1

Figure 1 above shows screws 2 and 3 extending through holes 15_1 and 15_2 in plate 1 to "secure the plate body 10 to the metatarsal M."[6] *Id.*¶ 33. "Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P." *Id.* ¶ 34. Screw 30 is inserted through hole 25 "following a direction of insertion inclined in relation to the plate body 10 at an angle . . . chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1" to join those bones. *Id.* ¶ 32; *see also id.* ¶ 6 (explaining that this screw "will extend both through the bone material of the phalanx and into the bone material of the metatarsal").

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[6] The labels for holes 15_1, 15_2, 15_3, 15_4, and 25 do not appear in Figure 1 of Arnould, but are shown in other figures depicting Arnould's plate. *See, e.g.*, Ex. 1006, Figs. 2, 4.

Arnould also teaches that "in order to allow the screw 30 to be screwed in and locked with its axis 31 inclined in relation to the central axis" of hole 25, that hole has "a concave surface which is substantially complementary to an associated surface delimited by this screw head." Ex. 1006 ¶ 27. Figure 4 of Arnould is reproduced below and provides an elevation view of plate 1 from another angle.

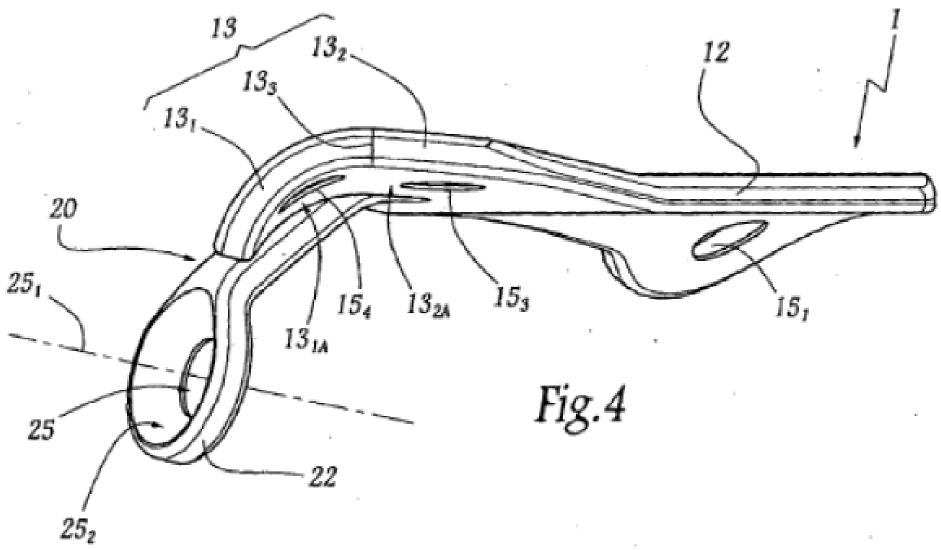


Figure 4 above shows hole 25 with a concave edge 25_2. *Id.* ¶ 27. According to Arnould, "when screw 31 is fully inserted into the hole 25, its head 32 comes to rest and wedge[s] against at least a portion of the edge 25_2." *Id.*

ii. Zahiri

Zahiri is a United States patent filed on September 26, 2006, and issued May 29, 2012. Ex. 1007, codes (22), (45). Petitioner asserts, and Patent Owner does not dispute, that Zahiri qualifies as prior art under 35 U.S.C. § 102(e). Pet. 11.

Zahiri describes "fixation devices for compressing bone fractures of a human being." Ex. 1007, 1:9–11. Figure 1 of Zahiri, reproduced below from

the version on page 11 of the Petition, depicts an embodiment of Zahiri's fixation device.

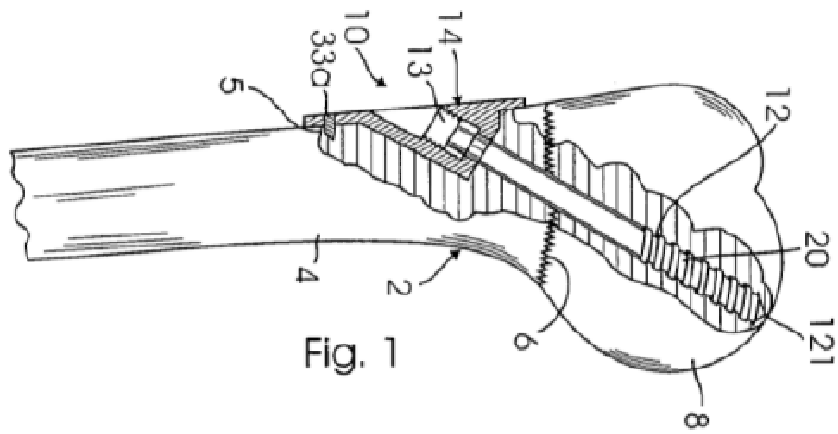


Figure 1 of Zahiri shows the insertion of lag screw 12 through guide plate 14 such that it extends through fracture line 6 in the bone at "an angle of 150 degrees or 170 degrees." *See id.* at 4:58–67. According to Zahiri, the inclined angle of the "short barrel portion" of the guide plate can vary in "the range of from 90 to 170 degrees." *Id.* at 3:59–67.

Zahiri also teaches that the plate may include holes for pins "designed to temporarily lock" the plate in position "so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." Ex. 1007, 3:11–18; *see also id.*, Fig. 8 (holes 235a-d).

iii. Myerson

Myerson is a United States patent application published on October 26, 2006. Ex. 1008, code (43). Petitioner asserts, and Patent Owner does not dispute, that Myerson qualifies as prior art under 35 U.S.C. § 102(b). Pet. 12.

Myerson describes "[a] fixation plate for use in fusion of the metatarsal-phalangeal joint" with a number of screw holes. Ex. 1008, code

(57). Myerson discloses an embodiment in which at least some of these "screw holes are designed to receive locking screws, such as by the incorporation of locking screws . . . within the screw hole." *Id.* ¶ 22. According to Myerson, "[t]he locking threads can be of a variety of known configurations as dictated by the particular cortical locking screw." *Id.*

E. Ground 4: obviousness over Arnould and Zahiri

Petitioner contends claims 32, 33, and 36–39 would have been obvious over Arnould and Zahiri. *See* Pet. 57–88. As explained below, Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over Arnould and Zahiri.

i. Claim 32

Petitioner contends that Arnould teaches or reasonably suggests all of the steps of the method in claim 32, including placement of a bone plate that spans a first and second bone separated by a joint (i.e., plate 10 having holes 15_3 and 15_4 aligned with the phalanx and holes 15_1 and 15_2 aligned with the metatarsal as depicted in Arnould's Figures 1 and 4), insertion of a first fixation member through a first hole of a plate into a first bone (i.e., screws 4 extending through holes 15_3 and 15_4 into the phalanx as depicted in Arnould's Figures 1 and 4), insertion of a second fixation member through a second hole into a second bone (i.e., screws extending holes 15_1 and 15_2 into the metatarsal as depicted in Arnould's Figures 1, 2, and 4), and insertion of a third fixation member seated in a third hole and extending through a thickness of the plate into both bones such that its free end resides in the second bone and is not attached to any portion of the plate (i.e., screw 30 with head 32 seated in the concave surface of hole 25 and extending into the

phalanx and metatarsal as depicted in Arnould's Figures 1 and 4.). Pet. 63–73 (citing evidence).

We find Petitioner's arguments and evidence persuasive. Arnould teaches a method of fusing a joint, e.g., the "metatarsal-phalangeal joint particularly . . . the joint between the first metatarsal and the first phalanx of the big toe," using the bone plate depicted in Arnould's figures. Ex. 1006 ¶ 1. As shown in Arnould Figure 1, reproduced below, bone plate 10 is positioned to span a joint between a first and second bone, specifically the phalanx P on the right and the metatarsal M, and has holes aligned with each of those bones (limitation 32[a]).

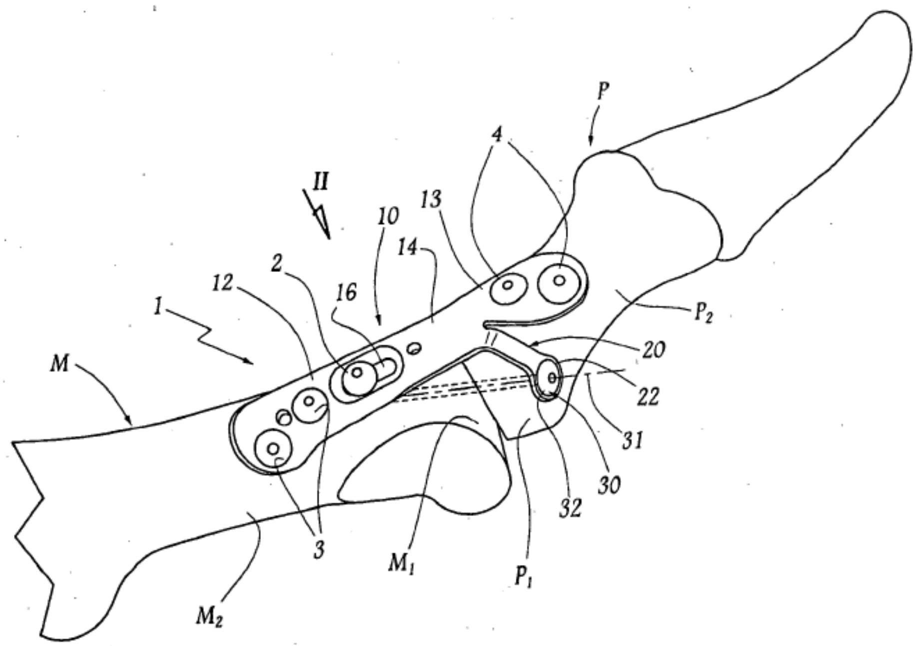


Fig. 1

As shown in the figure, screws 4 (i.e., "fixation member[s]" as recited in claim 32) are inserted through holes in the plate 10 into the first bone P (limitation [32b]) and screws 3 are inserted through holes in the plate 10 into the second bone M (limitation [32c]). *Id.* ¶¶ 33–34. Screw 30 is inserted through a hole in plate 10 into the first and second bone such that the free

end resides in the second bone and the head 32 of screw 30 resides in the hole (limitation [32d]). *Id.* ¶ 32. Moreover, as shown in Figure 1, screw 30 is the only fixation member that extends across the joint (limitation [32g]).

Arnould also teaches that the hole through which screw 30 extends is configured as recited in limitations [32e] and [32f]. Figure 4 of Arnould, reproduced below, shows hole 25, which Petitioner maps to the "third hole" in claim 32.

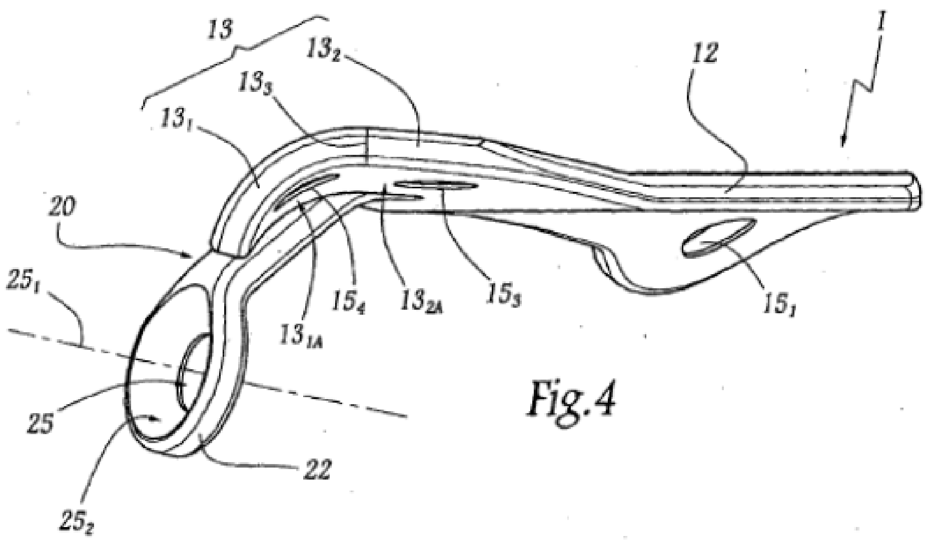
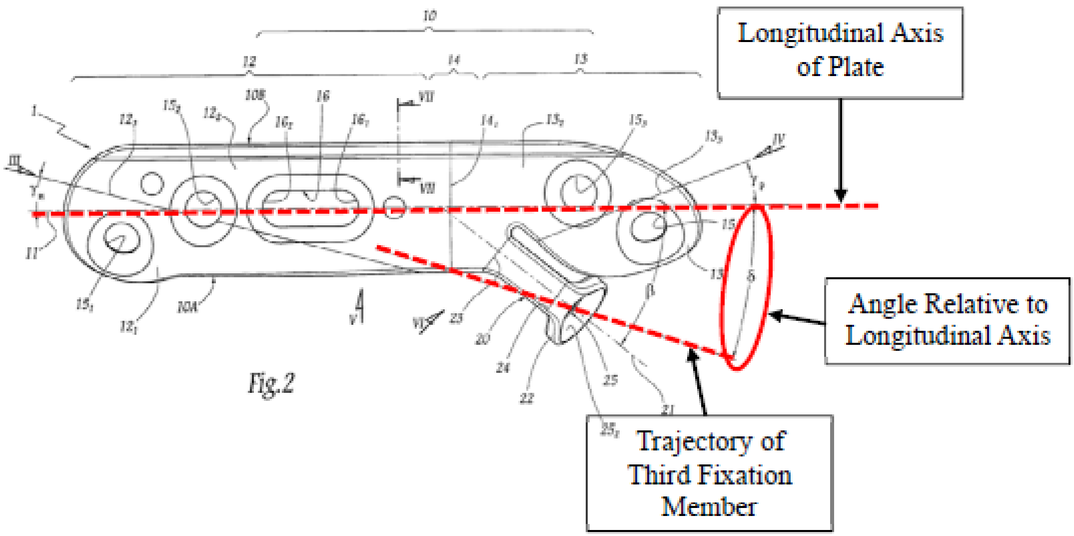


Fig.4

As shown in the figure, "the edge 25_2 of this hole has, on the side facing the head 32 of the screw [30], a concave surface which is substantially complementary to an associated surface delimited by this screw head." Ex. 1006 ¶ 27. In other words, when the screw is fully inserted, the head of the screw is seated within the hole (limitation [32e]). *Id.* Moreover, hole 25 is angled relative to the longitudinal axis and extends through a thickness in the plate as recited in limitation [32f]. This can be seen in the annotated version of Figure 2 of Arnould offered by Petitioner and reproduced below.



Petitioner adds red dotted lines demonstrating that the trajectory of the third fixation member (i.e., screw 30) through hole 25 is angled relative to the longitudinal axis of the plate.

Patent Owner contends that Arnould does not teach or suggest limitation [32f] because "while the trajectory of screw 30 may be angled, it does not follow that hole 25 is necessarily angled." Resp. 59. According to Patent Owner, "screw hole 25 is not angled 'through a thickness of the plate,' nor would a POSITA consider screw hole 25 to be angled 'through a thickness of the plate' as required by the claim. Rather, screw hole 25 appears to have the same geometry as screw holes 15_1, 15_2, 15_3, and 15_4." *Id.* at 59–60 (citing Ex. 1006, Figs. 1, 2, 4–6; Ex. 2005 ¶¶ 188–89).

We disagree with Patent Owner. The claim does not require that the third hole be at any particular angle, nor does it require that the hole limit the trajectory of the third fixation member to a particular angle relative to the longitudinal axis. All that is required is that the hole be "angled relative to a longitudinal axis of the plate through a thickness of the plate." Ex. 1001, 5:16–18. Such a configuration is unequivocally shown in Arnould's figures.

Figure 2 of Arnould shows that hole 25 is disposed at an angle to the longitudinal axis 11 of the plate.[7] Arnould explains that angle δ in Figure 2 is the angle of axis 31 (labeled in Figure 1) of screw 30 relative to the longitudinal axis 11 of the plate. Ex. 1006 ¶ 27. Arnould teaches that the concave surface of hole 25 "is substantially complementary to an associated surface delimited by" the head of screw 30 such that when the screw "is fully inserted into the hole 25, its head 32 comes to rest and wedge[s] against at least a portion of the edge 25_2, even if its axis 31 is inclined in relation to the axis 25_1 of the hole." Ex. 1006 ¶ 27. Thus, Arnould teaches that the axis 25_1 of hole 25 (labeled in Figure 4) may be "inclined in relation" to the axis of the screw or it may not be—in which case the axis of screw 30 and the axis of hole 25 would be at the same angle, i.e., angle δ, to the longitudinal axis 11 of the plate *Id.* In either event, the axis of Arnould's third hole is angled relative to the longitudinal axis of the plate and extends through the thickness of the plate, as recited in limitation [32f].

Arnould additionally discloses this limitation because the inner surface of hole 25 is angled relative to the longitudinal axis of the plate. As shown in Figure 4 of Arnould, the diameter of hole 25 on the outer surface of the plate is larger than the dimeter of the hole on the inner surface, resulting in a "concave surface" on the interior of hole 25. *See, e.g.*, Ex. 1006, Fig. 4, ¶ 27. As shown in Figure 4, this concave surface is "angled

[7] Figure 2 depicts angle β, which is described as the angle of the leg 20 relative to the longitudinal direction of the plate body, and angle δ, which is described as the angle of the longitudinal axis of screw 30 to the plate body. Ex. 1006 ¶¶ 25, 27.

relative to a longitudinal axis of the plate through a thickness of the plate" as recited in limitation [32f].

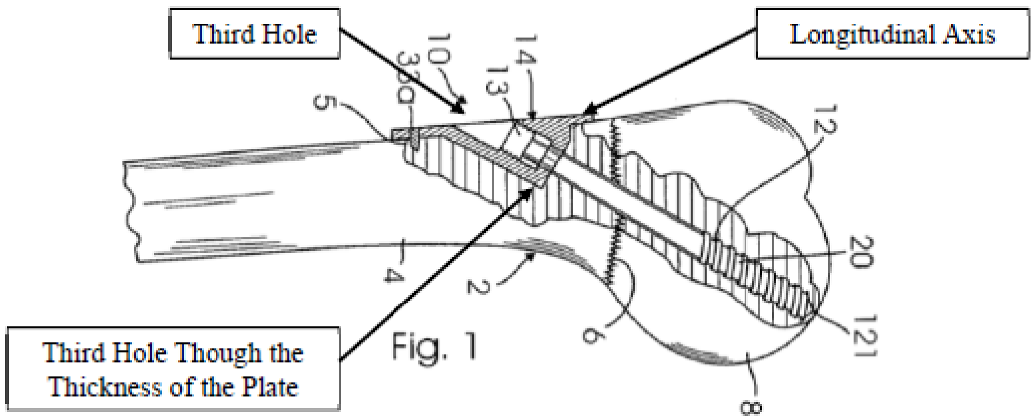
The testimony Patent Owner cites from Mr. Leinsing does not show otherwise. Mr. Leinsing's testimony appears to be premised on limitations not recited in the claim itself. *See* Ex. 2005 ¶¶ 188–89 (asserting that "[a]ngle β [in Arnould Fig. 2] is formed by the longitudinal direction 11 and longitudinal direction 21 of leg 20, not hole 25" and that "hole 25 is not an 'angled hole' as claimed"). Neither Patent Owner, nor Mr. Leinsing, squarely addresses the fact that Arnould's figures show that both hole 25 and the concave inner surface of that hole are disposed at an angle to the longitudinal axis of the plate. *Id.* In contrast, Mr. Sherman's testimony is consistent with the figures and written description in Arnould. Ex. 1002 ¶¶ 218–20. Accordingly, we find Mr. Sherman's testimony on this point to be more credible than the competing testimony from Mr. Leinsing.

For these reasons, Petitioner has demonstrated that Arnould teaches or suggests all of the limitations of claim 32. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 32 would have been obvious over Arnould alone.

We also address Petitioner's alternative theory that claim 32 would have been obvious over the combination of Arnould and Zahiri.[8] For this theory, Petitioner relies on Zahiri as additional evidence that a third hole

[8] The Petition explains that the proposed combination of Arnould with Zahiri is an alternative basis for the unpatentability of claim 32, i.e., "[t]o the extent that Arnould is found to not explicitly disclose" limitation [32f]. Pet. 70; *see also* Reply 25 (explaining that Arnould meets the requirements of claim 32 "without turning to the disclosure of Zahiri, which renders [Patent Owner's] challenges to the combination with Zahiri irrelevant").

configured as recited in limitations [32e] and [32f] would have been obvious. *See* Pet. 67–68, 70–71, 72–73. Petitioner illustrates its contentions with an annotated version of Figure 1 of Zahiri, which is reproduced below.



Petitioner annotates Figure 1 above to identify what it calls Zahiri's "third hole," which is angled relative to the longitudinal axis of plate 14 such that a screw inserted through the hole is positioned at an angle extending through two bone parts. *Id.* at 71. Petitioner contends "a POSITA would have readily looked to Zahiri for a way to improve the placement" and "integrity of the angled fixation screw" by using "the seated head of the lag screw from Zahiri." *Id.* at 67–68, 70–71. In other words, Petitioner proposes modifying hole 25 in Arnould's plate to incorporate the angled hole with a seated screw head configuration depicted in in Figure 1 of Zahiri (referred to hereinafter as "Zahiri's angled hole configuration"). *See id.* According to Petitioner, a POSITA would have been motivated to make this combination because Zahiri teaches that this arrangement "allows a sufficient amount of force to be applied between bone parts while dissipating the force so that it does not damage the bone parts" and a POSITA would have known that "bone plates configured for arthrodesis [like those taught in Arnould] and bone plates

configured to fuse bone fractures [like those taught in Zahiri] would be used interchangeably." *Id.* at 58–59 (citing Ex. 1007, 5:65–6:11; Ex. 1002 ¶ 193).

We again find Petitioner's arguments and evidence persuasive. Figure 1 of Zahiri shows "plate 14" having an angled hole extending through the thickness of the device with a screw inserted to join two bone parts wherein the free end of the screw resides in the second part and is not attached to the plate. Ex. 1007, Fig. 1, 4:58–67. The head of the screw is seated in the hole as recited in limitation [32e], the hole is disposed at an angle relative to the longitudinal axis of the device as recited in limitation [32f]. Zahiri teaches that this configuration is desirable because it dissipates compression forces, which avoids "failure by loosening of the device" and keeps the bone cortex "healthy and intact." *Id.* at 5:65–6:7. Moreover, Mr. Sherman provides testimony, which we credit, explaining that "bone plates configured for arthorodesis and bone plates configured to fuse bone fractures [like Zahiri's plate] have been used interchangeably for decades." Ex. 1002 ¶ 193. Thus, even if Arnould did not itself teach or suggest a third hole configured as recited in limitations [32e] and [32f], Petitioner has shown that its proposed combination of Arnould and Zahiri does and articulated reasoning with rationale underpinning demonstrating that a POSITA would have been motivated to make that combination with a reasonable expectation of success.

Patent Owner contends that Zahiri is not analogous art to the '713 patent and therefore cannot be combined with Arnould because Zahiri "discloses only a 'guide plate'" and not "a 'bone plate,' as properly defined." Resp. 35–36. According to Patent Owner, Zahiri's plate is not a "bone plate" because it "is designed to be positioned on only one side of a

fracture – it does not span any fracture, let alone a joint." *Id.* at 36; *see also* Sur-reply 23 (arguing that "under the proper construction of 'bone plate' . . . Zahiri is *not* a 'bone plate'"). Moreover, Patent Owner contends that "[t]he Zahiri device does not itself serve as structural support to immobilize the bone segments" and is designed for a "specific procedure." *See id.* at 36–37.

We disagree with Patent Owner for several reasons. First, the narrow construction of "bone plate" that Patent Owner proposes to distinguish Zahiri is not supported by the record. *See supra* § III.C. We agree with Petitioner that the ordinary meaning of "bone plate" includes plates like those described in Zahiri. *Id.* Second, even if Patent Owner's construction were correct, the scope of analogous art is broader than Patent Owner contends. A reference is considered to be analogous art if it is in the "same field of endeavor" as the patent at issue. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Here, the Specification states that "[t]he invention relates to the technical field of orthopedic implants." Ex. 1001, 1:18–19. Zahiri falls squarely within this field of endeavor, describing "fixation devices for compressing bone fractures of a human being." Ex. 1007, 1:9–11; *see also, e.g.*, *id.* at Fig. 1 (depicting the use of Zahiri's plate as an orthopedic implant to fix two bone parts). The differences Patent Owner identifies in Zahiri's device do not show otherwise.

In this regard, the testimony of Mr. Sherman (Ex. 1002 ¶ 191) on this point to be more credible than the competing testimony offered by Mr. Leinsing (*see* Ex. 2005 ¶¶ 124–31, 166). Mr. Sherman persuasively testifies that "Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone or across a fracture," demonstrating Arnould and Zahiri "are therefore in

analogous fields of invention" to the '713 patent. Ex. 1002 ¶ 191. Mr. Leinsing, on the other hand, asserts that Zahiri's plate is not a bone plate because it is located on only one side of a fracture and therefore does not "span[] both sides of a bone discontinuity." *See* Ex. 2005 ¶¶ 124–26, 131. For this reason, Mr. Leinsing concludes Zahiri is non-analogous art. *Id.* ¶ 131. Because we find Zahiri discloses a "bone plate" according to the ordinary meaning of that term, Mr. Leinsing's testimony is unconvincing. *See supra* § III.C. (explaining that the ordinary meaning of "bone plate" does not exclude plates located on only one side of a joint or fracture). But even if we agreed with Patent Owner's and Mr. Leinsing's interpretation of bone plate, Zahiri's plate is still an orthopedic implant and therefore analogous art because it is within the same field of endeavor as the '713 patent.

Patent Owner's argument that Zahiri teaches away from a combination with Arnould is also unavailing. *See* Resp. 54–57. Patent Owner asserts that unlike Arnould's plate, Zahiri's "rigid guide plate . . . does not allow a surgeon to conform the plate to the anatomy" and "[d]ue to the fixed angle design of Zahiri's device, the surgeon cannot select the angle of insertion of the lag screw to adapt to the individualized needs of a particular patient." *Id.* at 56. But those distinctions do not rise to the level of a teaching away. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009)) ("A reference does not teach away . . . if it . . . does not criticize, discredit, or otherwise discourage investigation into the invention claimed."). Moreover, Petitioner's combination is premised on modifying hole 25 in Arnould's plate to have

Zahiri's angled holed configuration. That combination would retain Arnould's flexible plate, while fixing or at least limiting the angle of screw 30 through the hole. However, Petitioner explains that "Zahiri discloses providing plates with a variety of angles in a kit so the surgeon can choose the plate that will maximize fixation based on the particular needs of the patient." Reply 21; *see also* Ex. 1007, 3:59–64, 9:1–4 (teaching that the hole may configured in a range of angles to accommodate the device's use "for a variety of fractures, fusion procedures and osteotomies"). Thus, a POSITA could compensate for the fixed angle and, in any event, the fact that one embodiment may be preferable in some instances does not teach away from the proposed combination. *See UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023) (explaining that a teaching that one composition is "optimal or standard" or that expresses a "preference" for something does not teach away from other options) (internal quotations omitted).

Patent Owner's remaining arguments against the combination of Arnould and Zahiri are also unavailing. Patent Owner contends there would have been no reasonable expectation of success because "adding the bulky Zahiri barrel to Arnould's thin, bendable leg simply would not work." Resp. 58 (citing Ex. 2005 ¶¶ 177–78). The problem with Patent Owner's argument is that it assumes the bodily incorporation of Zahiri's barrel without consideration of a POSITA's exercise of ordinary skill to apply Zahiri's teachings to Arnould's bone plate. It is well-established that a POSITA is understood to exercise "ordinary creativity" and is "not an automaton." *See KSR*, 550 U.S. at 421. Indeed, as our reviewing court recently observed, "a skilled artisan may be motivated to combine particular features of different references, e.g., to secure some benefits at the expense

of others, even when bodily incorporation would be impossible or inadvisable." *Axonics, Inc. v. Medtronic, Inc.*, No. 2022-1451, 2022-1452, slip op. at 12 (Fed. Cir. July 7, 2023).

This is the case here where Petitioner is proposing a relatively minor change to Arnould's plate, i.e., modifying the existing hole 25 in Arnould's plate to incorporate Zahiri's angled hole configuration. There is no indication this configuration would not work if adapted to and sized for the dimensions of Arnould's plate and the anatomy of the metatarsal-phalangeal joint through the exercise of a POSITA's ordinary creativity. Indeed, Mr. Sherman offers testimony, which we credit, demonstrating that plates for fusing fractures and joints were known to be interchangeable. *See* Ex. 1002 ¶ 193. We find that evidence sufficient under the facts of this case to demonstrate that a POSITA would have had a reasonable expectation of success. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 32 would also have been obvious over the combination of Arnould and Zahiri.

ii. Claim 33

Claim 33 depends from claim 32 and additionally recites that "the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate." Ex. 1001, 5:20–22.

Petitioner cites Arnould's teaching that angle δ is "less than 45" degrees. Pet. 74 (citing Ex. 1006 ¶ 27). For the combination of Arnould and Zahiri, Petitioner cites evidence that Zahiri also discloses an angle that "encompasses the claimed range." *See id.* at 75–77 (citing Ex. 1007, Fig. 4,

3:59–67; Ex. 1002 ¶¶ 229–31). Patent Owner does not dispute Petitioner's showing for claim 33 separately from its arguments for claim 32.[9]

We agree with Petitioner that Arnould and Zahiri disclose ranges for the angle of the third hole relative to the longitudinal axis of the plate that overlap with the range in claim 33. This overlap is sufficient to show that the range in claim 33 would have been obvious. *See E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) (explaining that "a prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art" and "such overlap creates a presumption of obviousness") (quotations omitted). Accordingly, Petitioner has shown by a preponderance of the evidence that claim 33 is unpatentable as obvious over Arnould and Zahiri.

iii. Claim 36

Claim 36 depends from claim 32 and additionally recites:

> wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

Ex. 1001, 6:3–9.

[9] Petitioner relies on its showing for claim 32 for each of the limitations the dependent claims incorporate by reference from claim 32. To the extent Patent Owner reasserts its arguments for claim 32 for the dependent claims, we find those arguments unavailing for the same reasons discussed above in our analysis of claim 32.

Petitioner contends that Arnould discloses this limitation. Pet. 78–79. Petitioner illustrates its contention with the annotated versions of Figures 1 and 2 of Arnould, reproduced below. *Id.* at 78.

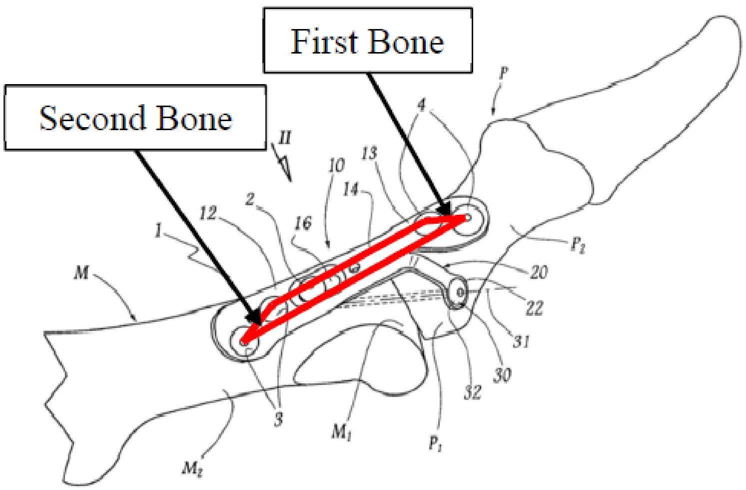


Fig. 1

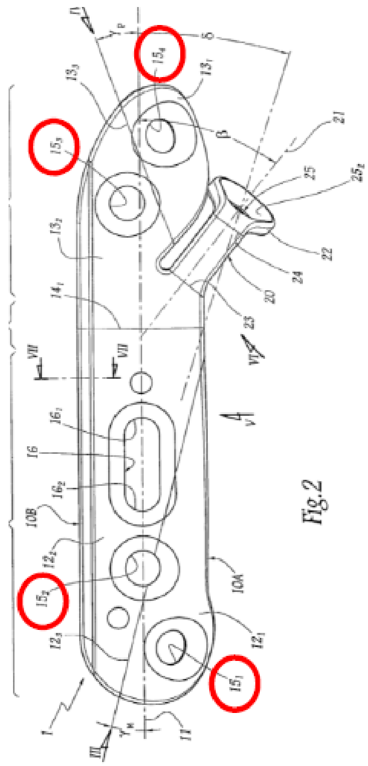


Fig. 2

The annotated figures above show "four holes 15_1-15_4 configured in a quadrilateral orientation" and marked with red circles in Figure 2, which "receive screws 3 and 4" highlighted by the red parallelogram Petitioner adds to Figure 1. *Id.* Petitioner explains that "[h]oles 15_1 and 15_2 are configured to receive screws 3 and attach to the metatarsal (second bone), and holes 15_3 and 15_4 are configured to receive screws 4 and attach to the phalanx (first bone)." *Id.* at 79. Petitioner additionally relies on Zahiri's disclosure of a similar "rectangular (i.e., quadrilateral) orientation" of holes for anchoring its plate to the bone. *See id.* at 79–80.

Patent Owner disputes Petitioner's showing based on its interpretation of claim 36. Patent Owner asserts:

> Claim 36 can be broken down in two parts: (1) "the plate includes a plurality of holes arranged according to the corners of a triangle or quadrilateral" and (2) "inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone." Part (2) informs a POSITA that claim 36 requires more than one "plurality of holes arranged according to the corners of a triangle or quadrilateral."

Resp. 22. According to Patent Owner, claim 36 requires more than one plurality of holes arranged in a triangle or quadrilateral because "part (2) recites 'inserting fixation members into ***each of*** the plurality of holes.'" *Id.* Patent Owner further contends that "because part (2) of claim 36 specifies that '***some*** of the fixation members extend into ***first*** bone while ***some*** of the fixation members extend into the ***second*** bone,'" one would understand that the claim is referring to at least one plurality of holes on the first bone and at least one plurality of holes on the second bone. *Id.* at 23. Moreover, Patent Owner urges that "[a] POSITA would understand that 'each of the plurality of holes' must be on the same side of the bone discontinuity in order to provide the 'stability of mounting' described in the '713 patent." *Id.* at 22 (quoting Ex. 1001, 2:53–55).

In reply, Petitioner argues that neither the claim language, nor the Specification, support Patent Owner's interpretation. According to Petitioner, the claim "requires '**a**' plurality of holes arranged according to the the corners of a triangle or of a quadrilateral,' not more than one plurality of holes" and "inserting fixation members into '**the** plurality of holes,' which is the singular plurality previously claimed." Reply 9. For this reason, Petitioner urges that the "fixation members inserted into the singular plurality of holes must have some extending into the first bone while others

extend into the second bone" and therefore "the triangular or quadrilateral configuration of holes **must** span the joint so that the screws can extend into both bones." *Id.* at 9–10. Petitioner contends that Patent Owner's interpretation renders the word "some" meaningless because Patent Owner "wants to read the claim as requiring all the fixation members for one plurality of holes be on one end and all of the other on the other end." *Id.* Petitioner argues "[t]his does not comport with the plain language" of the claim and is inconsistent with the interpretation Patent Owner advanced in its preliminary infringement contentions in the related district court proceeding. *Id.* (citing Ex. 1026, 32, 36).

In its sur-reply, Patent Owner argues that the final infringement contentions "developed in consultation with Mr. Leinsing" show that Patent Owner has "interpreted claim 36 in a manner consistent with this proceeding." Sur-reply 13 (citing Ex. 2024, 34–37). Patent Owner further contends that Petitioner's interpretation renders portions of the claim superfluous "because with a single 'plurality of holes' configuration, it would never be possible to have a triangular hole configuration with 'some of the fixation members extend[ing] into the first bone' while 'some of the fixation members extend into the second bone.'" *Id.* at 13–14.

We determine that Petitioner has the better position. "An indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more'." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (quoting *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000)). Indeed, our reviewing court has explained this

> is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must evince a clear intent to limit "a" or

> "an" to "one." The subsequent use of definite articles "the" or "said" in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning. An exception to the general rule that "a" or "an" means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.

Id. (internal citations omitted).[10] Here, claim 36 recites "***a*** plurality of holes arranged according to the corners of ***a*** triangle or of ***a*** quadrilateral." Thus, according to this rule of claim construction, claim 36 encompasses one or more plurality of holes arranged according to the corners of one or more triangles or one or more quadrilaterals.

The claim language in what Patent Owner calls part (2) of claim 36 is entirely consistent with this interpretation. The phrase "each of" indicates that fixation members are inserted into "each of the plurality of holes," i.e., a fixation member is inserted into each hole at the corner of the triangle or quadrilateral. This reading is more plausible than Patent Owner's interpretation, which creates a requirement for at least a second set of holes when the antecedent in part (1) refers to only "a" plurality of holes. Similarly, the requirement that "some" fixation members extend into each bone does not suggest that there must be more than one set of holes. Rather, the more natural reading in this context is that "some" means one or more.

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[10] In *Baldwin*, the Federal Circuit rejected an argument that the use of the indefinite article "a" in the phrase "a pre-soaked fabric roll" limited the claim to a single roll. *See* 512 F.3d at 1344. Patent Owner in this case raises a different argument, seeking to limit the phrase "a plurality of holes" to require more than one plurality. However, the general rule that "a" means "one or more" applies with equal, if not more, force here where we are asked to interpret claim 36 such that the singular meaning of the indefinite article would be excluded.

For a single triangular configuration of holes spanning the two bones, this means that claim 36 requires, at minimum, one screw in one bone and two screws in the other. Indeed, this is exactly how Patent Owner interpreted this claim language in the initial infringement contentions that Petitioner cites. *See* Ex. 1026, 33.[11]

Nor do we see a reason to depart from the general rule that "a" means one or more elsewhere in the intrinsic record of the '713 patent. All of the figures in the Specification depict a linear arrangement of holes. *See* Ex. 1001, Figs. 1–4. The only passage in the Specification Patent Owner identifies as relevant to claim 36 states that the holes "can be aligned or arrayed, all or in part, according to the corners of a triangle or of a quadrilateral. These provisions, in triangle or quadrilateral, of the screws, improve the stability of the mounting." Ex. 1001, 2:50–54. This passage says nothing about Patent Owner's alleged requirement that there be more than one set of holes in a triangle or quadrilateral pattern. To the contrary, the Specification, like claim 36, uses the indefinite article "a" to refer to "a triangle" and "a quadrilateral," which as a general matter would encompass a single triangular or single quadrilateral set of holes. Moreover, neither party identifies anything in the prosecution history relating to the interpretation of claim 36. Thus, there is nothing in the intrinsic record of the '713 patent that supports Patent Owner's attempt to depart from the "general rule" that "a" means "one or more," much less does the intrinsic record evince the "clear intent" required to "necessitate a departure from th[at] rule." *See Baldwin*, 512 F.3d at 1342.

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[11] The fact that Patent Owner subsequently changed these contentions does not suggest that its initial interpretation was incorrect or unreasonable.

The testimony Patent Owner cites from Mr. Leinsing is unpersuasive. *See* Resp. 22, 63 (citing Ex. 2005 ¶¶ 96–101, 194–97). As an initial matter, this testimony is extrinsic evidence and therefore does not provide a convincing reason to construe claim 36 as Patent Owner suggests. *See Baldwin*, 512 F.3d at 1342 ("An exception to the general rule that "a" or "an" means more than one only arises where the language of *the claims themselves, the specification, or the prosecution history* necessitate a departure from the rule.") (emphasis added). Second, this testimony is largely conclusory, repeating Patent Owner's claim construction arguments above, and concluding, without further explanation, that "a POSITA would recognize that each grouping of holes that makes up the 'plurality of holes arranged according to the corners of a triangle or quadrilateral' must be on the same side of the bone discontinuity." *See* Ex. 2005 ¶¶ 100–101. Third, Mr. Leinsing does not attempt to reconcile his testimony with the fact that claim 36 recites only "a" plurality of holes as antecedent. Accordingly, we do not find Mr. Leinsing's testimony credible regarding the proper interpretation of claim 36.

For these reasons, we interpret claim 36 to encompass one or more pluralities of holes arranged according to the corners of a triangle or quadrilateral, wherein fixation members are inserted into each of those holes with some of the fixation members extending into the first bone and some extending into the second bone.

Petitioner has shown that Arnould teaches this limitation.[12] As demonstrated by Petitioner's annotations to Figure 2 of Arnould, holes 15_1–

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[12] We do not need to reach Petitioner's additional argument that Zahiri separately teaches the additional limitation recited in claim 36.

15_4 of plate 10 are arranged according to the corners of a quadrilateral. Ex. 1006, Figs. 1–2. Arnould teaches that screws 4 are inserted into holes 15_3 and 15_4 and extend into the phalanx and screws 3 are inserted into holes 15_1 and 15_2 and extend into the metatarsal. *Id.* at Fig. 1, ¶¶ 33–34. Thus, Arnould teaches that some of the fixation members inserted into these holes extend into a first bone and some of those fixation members extend into the second bone. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 36 is unpatentable as obvious over Arnould and Zahiri.

iv. Claim 37

Claim 37 depends from claim 36 and additionally recites:

> wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

Ex. 1001, 6:11–16.

Petitioner contends that Arnould discloses this limitation. Pet. 80–82. According to Petitioner, Arnould's bone plate is contoured "to secure the metatarsal and phalangeal and to conform to the upper surface of the diphyseal portion of the metatarsal." *Id.* (citing Ex. 1006, Figs. 3–6, ¶¶ 15, 39). Petitioner further asserts that the screws 3 and 4 as well as screw 30 in Figure 1 of Arnould are angled relative to each other. *Id.* at 82; *see also* Reply 26–27 (arguing that "Arnould discloses a countered plate that would result in the identified fixation members in each end going in at different angles from one another").

In addition to reasserting its arguments for claims 32 and 36,[13] Patent Owner contends that "Petitioner's analysis of claim 37 is flawed." Resp. 65. According to Patent Owner, "the antecedent basis for the 'plurality of fixation members' is found in claim 36," and therefore screw 30 is "not one of the plurality of fixation members Petitioner identified in claim 36." *Id.*

We find Petitioner's arguments and evidence persuasive. Arnould teaches a bone plate that is "shaped to conform to the upper surface of the diaphyseal portion M_2 of the metatarsal M – that is to say, to come into contact with this diaphysis while partially covering it in a fitted manner, as shown in Figure 1." Ex. 1006 ¶ 15; *see also id.* ¶ 39 (teaching that the plate is "cut in accordance with predetermined contours in order to secure the metatarsal 12 and phalangeal 13 parts"). Thus, Arnould teaches a plate curved to adapt to the curvature of the first and second bones as recited in claim 37.

Because of this contour, at least some of screws 3 and screws 4 will be angled with respect to each other when inserted into their respective holes. For example, Figure 5 of Arnould, reproduced below, provides a side view of Arnould's plate with the longitudinal axis extending along the plane of the page.

[13] For the same reasons discussed above, these arguments are also unavailing for claim 37.

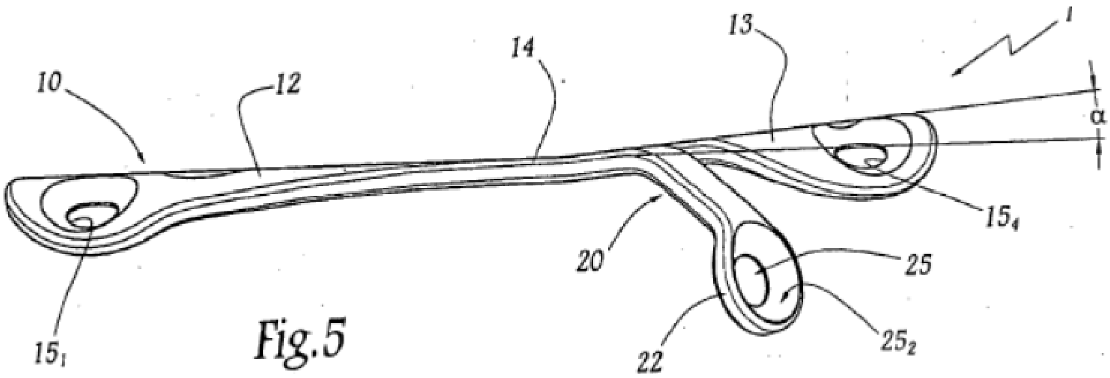


Fig.5

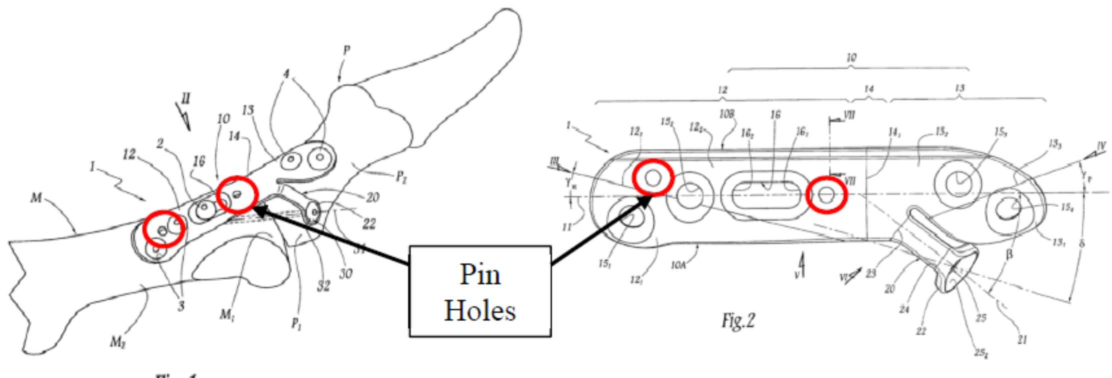
As shown in the figure above, holes 15_1 and 15_4 are positioned below the other holes along the plate's longitudinal axis. When screws 3 and 4 are inserted into these holes, as shown, e.g., in Figure 1 of Arnould, those screws will be at an angle relative to the screws inserted in the holes along the longitudinal axis. *See also, e.g.*, *id.* at Fig. 4 (depicting hole 15_4 at an angle to hole 15_3). Thus, even accepting Patent Owner's argument that the antecedent for the plurality of holes recited in claim 37 excludes consideration of hole 25 and screw 30, Petitioner has demonstrated that at least some of screws 3 and 4 will be angled with respect to each other and thus meet the limitations recited in claim 37. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 37 is unpatentable as obvious over Arnould and Zahiri.

v. Claim 38

Claim 38 depends from claim 37 and additionally recites the step of "inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone." Ex. 1001, 6:16–18.

Petitioner contends this limitation would have been obvious in view of Arnould. Pet. 83. Petitioner asserts that Arnould's "figures show pin holes that are used to temporarily secure the plate with k-wires during the

implantation process." Pet. 59–60, 82–83. Petitioner provides annotated versions of Figures 1 and 2 of Arnould, reproduced below, to illustrate this contention. *Id.* at 60.



In the annotated figures, Petitioner adds red circles to identify the pin holes shown in Figures 1 and 2 of Arnould. Petitioner acknowledges that "Arnould does not explicitly describe the use of k-wires," but argues that a POSITA would recognize these holes in Arnould's plate to be "pin holes" intended for this purpose because "K-wires are commonly used for temporary placement and immobilization of bone plates so that the surgeon can correctly position and align a plate." *Id.* at 83 (citing Ex. 1002 ¶¶ 194, 240).

Petitioner also asserts that Zahiri "discloses additional pins that 'are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." Pet. 83 (quoting Ex. 1007, 3:10–18); *see also id.* (annotating Figure 8 of Zahiri to identify "pin holes" in Zahiri's plate). According to Petitioner, such "[u]se of temporary fixation pins was common at the time of invention, and would have been readily utilized by a

POSITA given the explicit disclosure in Zahiri and the desire to temporarily secure Arnould's plate." *Id.* at 84 (citing Ex. 1002 ¶ 242).

Patent Owner argues that "Petitioner concedes, 'Arnould does not explicitly describe the use of k-wires," and "the holes that Petitioner refers to [in Figures 1 and 2] are never discussed in Arnould." Resp. 65–66 (quoting Pet. 82, citing Ex. 2005 ¶ 203).

Regarding Petitioner's argument that it would have been obvious to incorporate Zahiri's temporary guide pins and holes, Patent Owner argues that combination is "based on impermissible hindsight." Resp. 57. According to Patent Owner, "the Arnould plate is not at risk for unwanted torqueing or spinning because (1) it is contoured to the metatarsal and phalanx, with a leg wrapping around the phalangeal epiphysis, and (2) Arnould discloses a way to align the plate prior to insertion of the cross screw by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M." *Id.* (citing Ex. 1006 ¶ 31; Ex. 2007 ¶¶ 65, 44–45). For these reasons, Patent Owner contends that "proper alignment and partial immobilization during implantation is obtained in Arnould ***without*** the need for Zahiri's temporary fixation features." *Id.* at 58 (citing Ex. 2007 ¶¶ 63–66, 44–45; Ex. 2005 ¶ 182).

In Reply, Petitioner points out that Patent Owner does not dispute that both Arnould and Zahiri disclose pin holes as recited in claim 38. Reply 27. Petitioner urges that "the oblong holes [Patent Owner and its declarants] Dr. Holmes and Mr. Leinsing refer to allow for movement of the plate along the longitudinal axis (direction 11 shown in Figure 2), not stabilization of the plate." *Id.* According to Petitioner, the fact that Arnould also "includes the

smaller holes [identified in Petitioner's annotated figures] indicates k-wires or other temporary fixation devices would be used and would assist with placement." *Id.*

In its Sur-reply, Patent Owner reiterates its position, urging that Petitioner "conceded that Arnould does not disclose claim 38," and there is "no credible evidence that . . . a POSITA ***would*** have been motivated to include Zahir's so-called 'temporary pin holes.'" Sur–reply 32–33.

We find Petitioner's arguments and evidence persuasive. Mr. Sherman testifies that: (1) k-wires were "commonly used for temporary placement and immobilization of bone plates so that the surgeon can correctly position and align a plate"; and (2) a POSITA would have understood Arnould's figures to "show pin holes that are intended to be used to temporarily secure the plate with k-wires during the implantation process." Ex. 1002 ¶¶ 194, 240. Neither of Patent Owner's declarants dispute this testimony. *See* Tr. 64:3–11 (Patent Owner's counsel acknowledging there is "no testimony that [Mr. Sherman] is wrong" on these two points). Mr. Leinsing points out that "the holes that Mr. Sherman refers to are never discussed in Arnould," which is true. Ex. 2005 ¶ 203. However, the fact that Arnould does not expressly say what the holes Petitioner identifies in Figures 1 and 2 are used for does not rebut Mr. Sherman's testimony that a POSITA would understand them to be pin holes intended for use with k-wires to temporarily secure the plate to the bone during implantation, which was a common practice in the art. *See* Ex. 1002 ¶¶ 194, 240; *see also* Ex. 2009, 80:15–81:13 (additional testimony regarding the use of k-wires in the art). Accordingly, the preponderance of the evidence supports Petitioner's argument that Arnould itself reasonably suggests the step recited in claim 38.

Even if Arnould did not itself suggest such a step, we find that it would have been obvious to incorporate Zahiri's temporary fixation pins for use with Arnould's plate. Zahiri discloses the use of pins inserted through holes in the plate to temporarily fix the plate to the bone before the permanent screws are inserted. Ex. 1007, 3:10–18. Zahiri also teaches that those pins are removed after the screws are inserted. *Id.* at 7:63–66. Given that Arnould's plate already has pin holes that Mr. Sherman testifies are intended for use with k-wires, we agree with and credit Mr. Sherman's testimony that a POSITA would have been motivated to incorporate the temporary fixation pins expressly taught in Zahiri to ensure correct placement of Arnould's plate. *See* Ex. 1002 ¶¶ 194–96, 240–42.

Patent Owner's argument that there would have been no need for this combination because Arnould obtains proper placement via other mechanisms is unavailing. As an initial matter, Patent Owner's argument ignores the fact that Arnould's figures depict pin holes in the plate. *See* Ex. 1002, 194 (annotating Figures 1 and 2 of Arnould to identify the "pin holes"). If it were true, as Patent Owner asserts, that there is no need for temporary fixation pins given the configuration of Arnould's plate, then there would be no reason for those pin holes. Yet, those holes are clearly depicted in Arnould's figures, and Patent Owner offers no alternative explanation for their purpose. Moreover, the other mechanisms Patent Owner points to only provide for partial immobilization of the plate. *See* Ex. 1006 ¶ 31 (explaining that the plate is "partially immobilized using the oblong hole 16" and screw 2 "without tightening the screw head against the edge of the hole" so that the "plate body 10 remains displaceable in the direction 11 relative to the metatarsal M"); Ex. 2005 ¶¶ 44–45 (annotating

hole 16 and screw 2 in Figure 1 of Arnould and explaining how this mechanism "partially immobilize[s]" the plate body during surgery while allowing the plate to remain displaceable in direction 11). The fact that Arnould teaches that its plate is partially immobilized using hole 16 and screw 2 does not obviate the motivation to use k-wires or incorporate Zahiri's temporary fixation pins to further immobilize the plate, either before or after the insertion of screw 2, to ensure correct alignment. For these reasons, we find Mr. Sherman's testimony (Ex. 1002 ¶¶ 194–97, 240–43) to be more credible then the competing testimony Patent Owner cites from Mr. Leinsing and Dr. Holmes (Ex. 2005 ¶ 182; Ex. 2007 ¶¶ 44–45, 63–66).

Accordingly, Petitioner has shown by a preponderance of the evidence that claim 38 is unpatentable as obvious over Arnould and Zahiri.

vi. Claim 39

Claim 39 depends from claim 32 and additionally recites "the joint is one of the anatomical joints of the human body in the foot or hand." Ex. 1001, 6:19–20.

Petitioner assert that "Arnould discloses a bone plate for arthrodesis of the metatarsophalangeal joint which is a joint within the foot." Pet. 85 (citing Ex. 1006, Fig. 1, ¶ 5; Ex. 1002 ¶ 244). Patent Owner does not dispute Petitioner's showing for claim 39 separately from its arguments for claim 32.

We agree with Petitioner that Arnould discloses the use of its bone plate for arthrodesis of a joint in the foot. Ex. 1006, Fig. 1 (depicting implantation of plate 10 across the metatarsal-phalangeal joint), ¶ 5; Ex. 1002 ¶ 244. Accordingly, Petitioner has shown by a preponderance of

the evidence that claim 39 is unpatentable as obvious over Arnould and Zahiri.

F. Ground 5: obviousness over Arnould, Zahiri, and Myerson

Petitioner contends claims 34 and 35 would have been obvious over Arnould, Zahiri, and Myerson. *See* Pet. 86–88. Claim 34 depends from claim 32 and additionally recites that "the first and second holes are locking holes." Ex. 1001, 5:23–24. Claim 35 depends from claim 34 and further recites that those "holes are threaded." *Id.* at 6:1–2. For the limitations incorporated from independent claim 32, Petitioner relies on the same showing discussed above for Ground 4. Pet. 87. Petitioner relies on Myerson for its teaching regarding locking and threaded holes. *Id.* at 87–88. According to Petitioner, "Myerson identifies a known method for securing screws and preventing screws from backing out: use of locking screws with locking threaded holes." *Id.* at 88 (citing Ex. 1008 ¶ 22). Petitioner argues "a POSITA would have been motivated to combine this teaching from Myerson with Arnould's plate . . . because the use of locking screws with locking threaded holes [was] a known technique to prevent the screws from backing out" and, therefore, Myerson "provides a solution and a predictable result . . . to the known problem of screws loosening and backing out over time." *Id.* (citing Ex. 1002 ¶¶ 250–52).

We find Petitioner's arguments and evidence persuasive. Myerson describes a bone plate for fusion of the "metatarso-phalangeal (MTP) joint," i.e., the same joint on which Arnould teaches its plate is used. Ex. 1008, code (57), Fig. 1, ¶¶ 1–2. Myerson teaches that in one embodiment, the screw holes in its plate are "designed to receive locking screws, such as by

the incorporation of locking threads . . . within the screw hole." *Id.* ¶ 22. Thus, Myerson teaches the additional limitations recited in claims 34 and 35 for use in the same kind of bone plate taught in Arnould.

Moreover, Mr. Sherman testifies that the use of locking screws with locking threaded holes was a predictable solution to the known problem of screws loosening and backing over time. Ex. 1002 ¶¶ 251–52. This testimony is supported by teachings in Myerson and other references cited by Petitioner. *See* Ex. 1004, 2:9–14 (noting that screws can "unscrew[] from the bone pieces and mov[e] out of the fixation plate once and after the fixation plate and screws have been firmly installed in the bones"); Ex. 1008 ¶ 22 (explaining that "[t]he locking threads can be of a variety of known configurations"). Accordingly, we find Mr. Sherman's testimony credible and persuasive to show that it would have been obvious to incorporate Myerson's threaded locking holes in Arnould's plate with a reasonable expectation of success.

In addition to its arguments for claim 32 in Ground 4, which are unavailing for the reasons discussed above, Patent Owner argues that "Petitioner has not demonstrated a motivation to combine Arnould, Zahiri, and Myerson." Resp. 66. According to Patent Owner,

> Petitioner relies on its flawed motivation to combine analysis of Arnould and Zahiri from Ground 4 and separately contends that a POSITA would be motivated to combine the teachings of Myerson to modify the Arnould bone plate. However, Petitioner never demonstrates that a POSITA would have been motivated to combine all three references together.

Id. at 66–67 (internal citations omitted).

We disagree with Patent Owner. While it is true, as Patent Owner points out, that our reviewing court has "reversed Board decisions that found

a motivation to combine where the petitioner presented only threadbare arguments to support its combination, let alone where a party entirely failed to address one of the references it sought to combine," those are not the situation here. *See* Resp. 67 (quoting *Apple Inc. v. MPH Techs. Oy*, No. 2021-1355, 2022 WL 4103286, at *7 (Fed. Cir. Sept. 8, 2022) ("*MPH Techs*").[14] Rather, as explained above, Petitioner has articulated sufficient reasoning with rationale underpinning for combining both Zahiri's angled hole configuration and Myerson's threaded locking holes with Arnould's plate.

Moreover, even if Petitioner's rationale and associated showing for combining Zahiri with Arnould were not sufficient, Petitioner has shown that Arnould alone teaches or suggests all of the limitations of claim 32. *See supra* § III.E.i. Thus, claims 34 and 35 would have been obvious over Arnould and Myerson even without the teachings in Zahiri. Accordingly, Petitioner has shown by a preponderance of the evidence that claims 34 and 35 are unpatentable as obvious over Arnould and Myerson with or without Zahiri.

G. Grounds 1–3

Having determined that all of the challenged claims are unpatentable as obvious over the references in Grounds 4 and 5, we need not reach

[14] In *MPH Techs*, the petitioner did not cite or address a reference, Ahonen, in its grounds for certain dependent claims even though those claims depended from a claim in another ground relying on Ahonen. 2022 WL at *7. Thus, that case dealt with a situation "where a petitioner did not address all of a claim's limitations in its petition." *Id.* at *8. Here, however, Petitioner addresses all of the limitations of claims 34 and 35, including those incorporated from claim 32.

Petitioner's argument that those same claims are also unpatentable as obvious over the references in the Grounds 1–3. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims"). Accordingly, we do not reach those grounds.

H. Patent Owner's Objections to Demonstratives

Patent Owner filed objections to certain demonstrative slides that Petitioner served for the oral hearing. *See* Paper 35, 1–2. Most, if not all, of Patent Owner's objections are moot because they relate to slides for grounds we do not reach in this decision. In any event, Petitioner's demonstratives are not evidence and we do not rely on them herein. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019), 84 (explaining that demonstratives are merely "aids to oral argument and not evidence" and therefore "the Board has not found that such objections are helpful in many cases"). Thus, we do not sustain Patent Owner's objections.

IV. CONCLUSION[15]

Petitioner has shown, by a preponderance of the evidence, that claims 32–39 of the '713 patent are unpatentable.

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[15] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
32, 33, 36, 37[16]	103	Slater		
34, 35, 39[17]	103	Slater, Myerson		
32, 33, 38[18]	103	Slater, Zahiri		
32, 33, 36–39	103	Arnould, Zahiri	32, 33, 36–39	
34, 35	103	Arnould, Zahiri, Myerson	34, 35	
Overall Outcome			32–39	

V. ORDER

Accordingly, it is:

ORDERED that Petitioner has shown that claims 32–39 of U.S. Patent 9,078,713 B2 are unpatentable;

Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

[16] As explained above, we do not reach this ground. *See supra* § III.G.
[17] As explained above, we do not reach this ground. *See supra* § III.G.
[18] As explained above, we do not reach this ground. *See supra* § III.G.

FURTHER ORDERED that Patent Owner's objections to Petitioner's Demonstrative Slides (Paper 35) are not sustained; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Jason Engel
Katherine Allor
K&L GATES LLP
jason.engel.ptab@klgates.com
katy.allor@klgates.com

For PATENT OWNER:

Sharon Hwang
Robert Surrette
Scott McBirde
MCANDREWS, HELD & MALLOY, LTD.
shwang@mcandrews-ip.com
bsurrette@mcandrews-ip.com
smcbride@mcandrews-ip.com

Trials@uspto.gov
571-272-7822

Paper No. 35
Date: August 8, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00488
Patent 10,993,751 B1

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and
MICHAEL A. VALEK, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

OsteoMed LLC ("Petitioner") filed a Petition (Paper 1, "Pet."), seeking *inter partes* review of claims 1–3 and 6–18 of U.S. Patent No. 10,993,751 B1 (Ex. 1001, "the '751 patent"). We instituted trial on all grounds in the Petition. Paper 8, 37.

Following institution, Stryker European Operations Holdings LLC ("Patent Owner") filed a Response (Paper 16, "Resp."), Petitioner filed a Reply (Paper 25, "Reply"), and Patent Owner filed a Sur-reply (Paper 29, "Sur-reply"). We held a hearing on May 11, 2023, and a transcript is of record. Paper 34 ("Tr.").

After considering the parties' arguments and evidence, we find that Petitioner has shown by a preponderance of the evidence that the challenged claims of the '751 patent are unpatentable. *See* 35 U.S.C. § 316(e). Our reasoning is explained below.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies OsteoMed LLC, Acumed LLC, and Colson Medical, LLC as real parties in interest. *See* Pet. viii. Petitioner additionally identifies Marmon Holdings, Inc. and Berkshire Hathaway Inc. as "parties that may be relevant to the determinations." *Id.* Patent Owner identifies Stryker European Operations Holding LLC, Stryker Corporation, and Howmedica Osteonics Corp. *See* Paper 14, 2.

B. Related Matters

Petitioner and Patent Owner identify *OsteoMed LLC v. Stryker Corporation*, 1:20-cv-06821 (N.D. Ill.) as a related matter. Pet. ix; Paper 14,

2. Patent Owner additionally identifies *OsteoMed LLC v. Wright Medical Technology, Inc.*, 1:20-cv-01621 (D. Del.). Paper 14, 3.

Petitioner also identifies IPR2022-00486 and IPR2022-00487, which were filed concurrently with the Petition and involve the same parties. Pet. ix. We denied institution in IPR2022-00486. *See* IPR2022-00486, Papers 8, 12. IPR2022-00487 is currently pending.

C. The '751 Patent

The '751 patent issued on May 4, 2021, and is a continuation of an application that is part of a series of continuation applications, the earliest of which was filed on October 2, 2008. Ex. 1001, codes (30), (45), (63).

The '751 patent relates to "a plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of said plate" that is configured to bring "the two bone parts into a compressive position." Ex. 1001, code (57). Figure 3 of the '751 patent provides a perspective view of this plate and is reproduced below. *See id.* at 2:1–4.

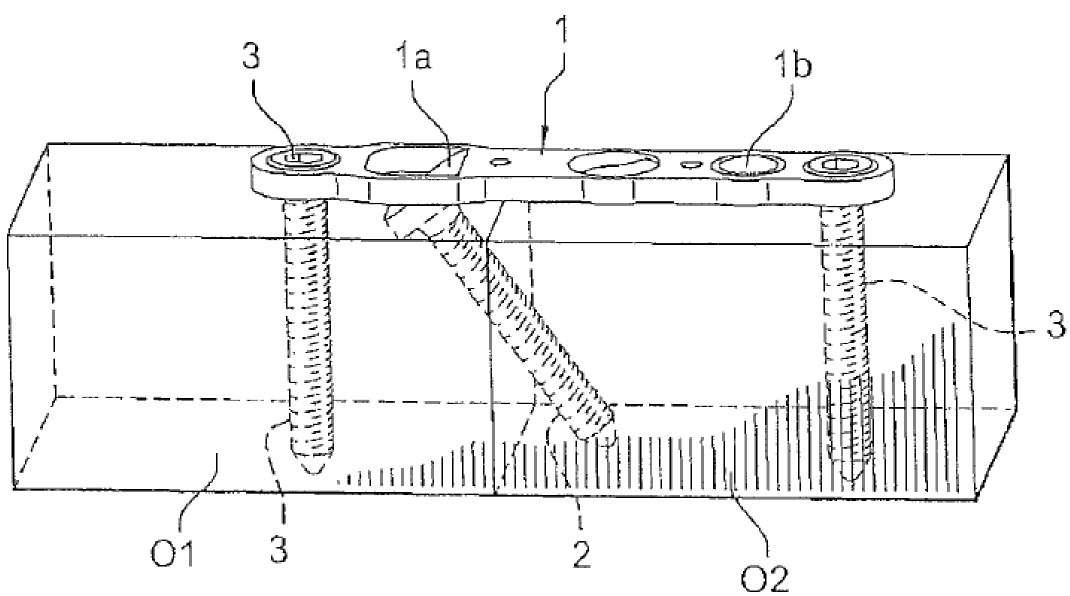


Fig. 3

Figure 3 depicts a plate 1 positioned between two bone parts O1 and O2. Ex. 1001, 2:28–29. Screws 3 are set through holes in the plate to attach it to bone parts O1 and O2. *Id.* at 2:45–47. A third screw 2 is positioned at an angle through a hole in tab 1a such that it extends through both parts O1 and O2. *Id.* at 2:8–11, 2:40–41. According to the Specification, engaging screw 2 in this manner "place[s] the fracture in compression." *Id.* at 2:40–41.

D. Challenged Claims

The Petition challenges claims 1–3 and 6–18. *See* Pet. 5. Challenged claims 1, 11, and 17 are independent. *See* Ex. 1001, 3:7–36 (claim 1), 3:61–4:29 (claim 11), 4:42–67 (claim 17). Claim 1 is illustrative of the challenged claims. Claim 1 is reproduced below with the same bracketed annotations used in the Petition to identify particular limitations.

> 1. [1pre] A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:
>
> > [1a] a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:
> >
> > [1b] a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint;
> >
> > [1c] a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and
> >
> > [1d] a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate;

> [1e] a first fixation member configured to be inserted through the first hole of the bone plate and into the first discrete bone of the joint;
>
> [1f] a second fixation member configured to [sic] inserted through said second hole of said bone plate and into the second discrete bone of said joint; and
>
> [1g] a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in a second discrete bone,
>
> [1h] wherein said third fixation member is the only fixation member extending across said joint from the first side of the joint to the second side of the joint.

Ex. 1001, 3:7–36.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	**35 U.S.C. §**[1]	**Reference(s)/Basis**
1, 2, 7, 8	103(a)	Slater[2]
1, 2, 7–18	103(a)	Slater, Zahiri[3]
6	103(a)	Slater, Zahiri, Myerson[4]

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. § 103 that became effective after the filing of the applications to which the '751 patent claims priority. Therefore, we apply the pre-AIA version of § 103.
[2] WO 2007/131287 A1, published November 22, 2007 (Ex. 1004) ("Slater").
[3] US 8,187,276 B1, filed September 26, 2006 and issued May 29, 2012 (Ex. 1007) ("Zahiri").
[4] US2006/0241592 A1, published October 26, 2006 (Ex. 1010) ("Myerson")

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1–3, 7–18	103(a)	Arnould,[5] Zahiri
6	103(a)	Arnould, Zahiri, Myerson

Pet. 5.

In support of these grounds, Petitioner relies on the declaration of Michael Sherman (Ex. 1002) submitted with the Petition. Patent Owner relies on declarations from Karl R. Leinsing (Ex. 2005) and George B. Holmes (Ex. 2007) submitted with the Patent Owner Response.

Our analysis below focuses on Grounds 4 and 5, i.e., the two grounds relying on Arnould instead of Slater. Grounds 4 and 5 collectively reach all of the challenged claims.

III. ANALYSIS OF THE ASSERTED GROUNDS

A. Legal Standards

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level

[5] EP 1,897,509 B1, published March 12, 2008 (Ex. 1005). Exhibit 1006 is a certified translation of EP 1,897,509 B1, which we cite and refer to herein as "Arnould."

of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Subsumed within the *Graham* factors is the requirement that the skilled artisan would have had a reasonable expectation of success in combining the prior art references to achieve the claimed invention. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). "Obviousness does not require absolute predictability of success . . . . [A]ll that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988). Moreover, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416.

On the other hand, a patent claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. An obviousness determination requires finding "both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted).

B. Level of Ordinary Skill in the Art

Relying on the testimony of its declarant, Mr. Sherman, Petitioner contends that a person of ordinary skill in the art (POSITA) of the '751 patent

> as of October of 2009, had at least a Bachelor's Degree in mechanical engineering, biomedical engineering, biomechanics or similar discipline and had approximately three years of

> experience with orthopedic implant design. Such a POSITA would have had knowledge of design considerations known in the industry and would have been familiar with then-existing products and solutions. A POSITA would have been familiar with orthopedic implants, bone plates, and intramedullary implants.

Pet. 4 (citing Ex. 1002 ¶¶ 50–52).

In its Response, Patent Owner argues:

> In pending IPRs involving Petitioner's own patents relating to the same bone plate technology, the parties and the Board agreed that "a POSITA at the time of the invention would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon."

Resp. 7–8. Patent Owner urges that for consistency the same level of ordinary skill in the art should apply here. *Id.* at 8.

Patent Owner disagrees with Petitioner's proposal to the extent it "excludes 'clinical practitioners with a medical degree and at least two years of experience as an orthopedic surgeon.'" Resp. 8 (internal quotations omitted). Patent Owner argues that "Petitioner's omission of clinical practitioners from its definition of a POSITA appears to be an oversight because Petitioner's expert . . . agreed at his deposition that orthopedic surgeons should be included within the definition of a POSITA." *Id.* (citing Ex. 2009, 38:21–39:17).

Petitioner did not respond to Patent Owner's argument regarding the level of ordinary skill in the art in its Reply and confirmed at the hearing that it does not dispute Patent Owner's proposed description. *See* Tr. 62:3–16.

While both parties' descriptions are similar, we find that Patent

Owner's description is better supported by the record. As Patent Owner points out, the main distinction between the parties' proposals is that Patent Owner's description is broader because it includes orthopedic surgeons. The record supports the inclusion of such individuals in the description of a POSITA. *See* Ex. 2005 ¶¶ 37, 41; Ex. 2009, 38:21–39:7 (Petitioner's declarant testifying that he would "include an orthopedic surgeon that has some experience developing implants as a person of ordinary skill in the art"). Thus, we apply Patent Owner's description of a POSITA for our analysis.

C. Claim Construction

Petitioner asserts that no term needs to be construed, *see* Pet. 5, but Patent Owner argues that we should construe the term "bone plate," which it asserts is a missing limitation in the asserted art, *see* Resp. 9–11. More specifically, Patent Owner argues that "[b]ecause Petitioner fails to define certain claim terms, its obviousness analysis glosses over claim limitations that are not met by the prior art." *Id.* at 9.

Patent Owner alleges that the '751 patent "defines the claim term 'bone plate' as 'a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts.'" *Id.* at 9 (quoting Ex. 1001, 1:29–31). Patent Owner further describes the "bone plate" by referring to the ordinary meaning of the claim terms "first end," "second end," and "between." *Id.* at 10–11. Patent Owner asserts that "a POSITA would have understood the claimed 'first end' to refer to one end of the bone plate and the 'second end' to include the opposite extreme end of the bone plate." *Id.* at 10 (citing Ex. 2005 ¶¶ 29–35). Patent Owner further asserts that a POSITA would

understand the claimed "third hole" located "between" a first and second hole to refer to "a 'third hole' located in the space separating the first hole and the second hole." *Id*. at 10–11 (citing Ex. 2005 ¶¶ 29–33, 36). We address the construction of these terms in turn below.

i. "Bone Plate"

Patent Owner contrasts its definition of "bone plate" with the device disclosed in Zahiri, which "is designed to be positioned on only one side of a fracture – [such that] it does not span any fracture, let alone a joint." *See id.* at 26 (urging that Zahiri "does ***not*** disclose a 'bone plate,' as properly defined") (citing Ex. 2005 ¶ 124). According to Patent Owner, we can "resolve the controversy regarding the meaning of 'bone plate'" by "determin[ing] that the claim term 'bone plate' refers to a 'a plate adapted to be fixed ***between two bone parts*** to immobilize a fracture or joint.'" *Id*. at 10.

Petitioner generally disputes Patent Owner's position, urging that the Specification does not define the term differently than its plain and ordinary meaning. Reply 3. According to Petitioner, none of the "dictionary definitions [Patent Owner cites] require that the plate itself cross the fracture or joint to be fixed." *Id*. at 4 (citing Ex. 2012, 5; Ex. 2013, 4). Moreover, Petitioner points to Mr. Sherman's testimony and other evidence that bone plates for fracture fixation are "not always" placed across the fracture. *Id*. (citing Ex. 2009, 52:9–53:1; Ex. 1019). Accordingly, Petitioner contends that "[t]o the extent 'bone plate' requires construction, it must include plates that are positioned on one side of a joint or fracture consistent with the term's plain and ordinary meaning." *Id*. at 5.

We begin by observing that Patent Owner does not dispute that both Arnould and Slater disclose a "bone plate" regardless of how the term is construed. *See* Tr. 41:1–6. Rather, Patent Owner seeks to construe "bone plate" to further its attempt to show that Zahiri is not analogous art, and therefore, cannot be combined with the other references. As explained below, we find that Zahiri is analogous art even if we were to adopt Patent Owner's proposal limiting "bone plate" to a plate "adapted to be fixed between two parts to immobilize a fracture or joint" because it is in the same field of endeavor, i.e., orthopedic implants, as the '751 patent. *Infra* § III.E.i.

That said, we do not agree with Patent Owner that the Specification defines "bone plate" as it contends. In the background of the invention, the Specification states that "[t]he invention relates to the technical field of orthopedic implants. More particularly, the invention relates to a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts." Ex. 1001, 1:27–31. Contrary to Patent Owner's argument, this passage does not "define" the term "bone plate" nor otherwise suggest that the patentee acted as its own lexicographer. *See* Resp. 9.

Moreover, nothing in the record suggests that the ordinary meaning of "bone plate" requires the plate to be fixed between two bone parts. The medical dictionaries Patent Owner cites do not include such a requirement in their definitions. *See* Ex. 2012, 1478 (defining "bone plate" as "a metal bar with perforations for the insertion of screws, used to immobilize fractured segments"); Ex. 2013, 241 (defining "bone plate" as "a metal plate used to reconstruct a bone that has been fractured" and "designed to hold the bone fragments in apposition"). Both of these definitions are consistent with Mr. Sherman's testimony that a bone plate is "not always" placed across the

fracture. *See* Ex. 2009, 52:9–53:1 (identifying particular instances in which a plate is not placed across the fracture). We credit that testimony over the competing testimony of Patent Owner's declarant, Mr. Leinsing. Ex. 2005 ¶ 34 (referring to the statements from the Specification and dictionary definitions discussed above).

For these reasons, we agree with Petitioner that the term "bone plate" as recited in the challenged claims has its ordinary meaning and that meaning does not exclude plates located on only one side of a joint or fracture.

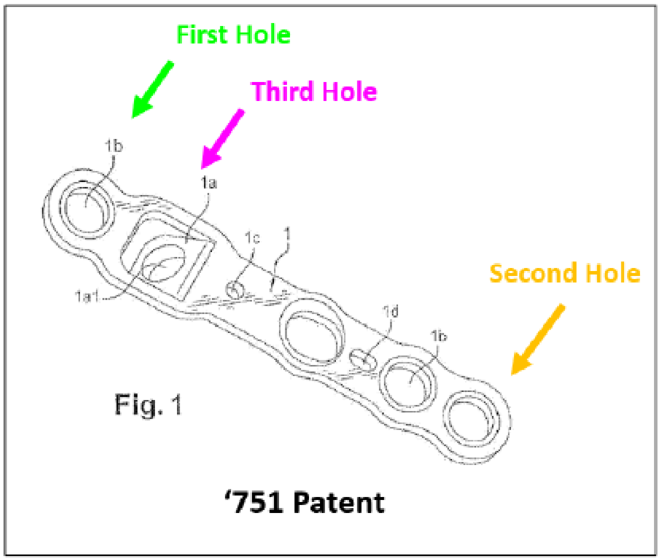
ii. "First End" and "Second End"

Patent Owner asks for a construction of the terms "first end" as referring to "one end of the bone plate" and "'second end' to include the opposite extreme end of the bone plate." Resp. 10. Petitioner asserts that such an interpretation "is at odds with the intrinsic evidence and with [Patent Owner's] interpretation of 'end' in other proceedings." Reply 5. Petitioner offers "[t]o the extent 'end' requires construction, it must include more than just the tip of a bone plate, i.e., a portion of the plate." *Id.* at 7.

In its Sur-Reply, Patent Owner indicates that the construction of these two terms "is necessary because the Board identified the mid-portion of the Slater plate as the 'second end.'" Sur-reply 8. Because we do not reach the Slater grounds in this decision, it is not necessary for us to resolve the parties' dispute regarding these terms and therefore we do not provide an express construction of the claim terms "first end" and "second end."

iii. "Between"

Patent Owner asserts that the ordinary meaning of the term "between" as used in the claim phrase "a third hole located between said first hole and said second hole" would be understood by a POSITA to mean "a 'third hole' located in the space separating the first hole and the second hole." Resp. 10–11 (citing Ex. 2005 ¶¶ 29–33, 36). Patent Owner asserts that such a construction is consistent with Figure 1 of the '751 patent as shown below.



Resp. 11. Figure 1 of the '751 patent, as annotated by Patent Owner, shows a first hole and a second hole on opposite ends of the bone plate with a third hole located along the bone plate between those two holes.

Petitioner disagrees. During Mr. Leinsing's deposition, Petitioner states:

> [I]t became clear PO's interpretation of "between" is extraordinarily narrow, excluding from the definition of between anything that is in a "different plane" or "offset." Ex. 1015, 151:8–20. Under PO's proposed definition, he explained, a person's hand is not "between" their head and their feet. *Id.*, 153:1–12.

Reply 7–8.

Petitioner relies on Figure 2 of the '751 patent to show that Patent Owner's definition is too narrow. Figure 2 of the '751 patent as annotated by Petitioner is depicted below.

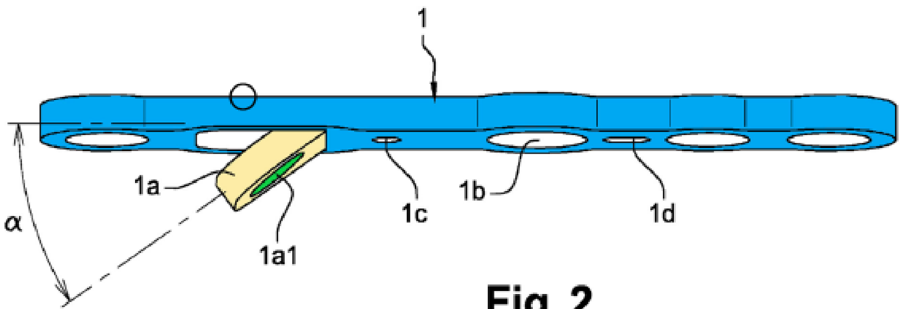


Fig. 2

Reply 8. Petitioner explains how the third hole 1a1 lies between the first and second ends of the bone plate even though it does not lie in the same plane as the other holes and is offset from the axis of the bone plate. Petitioner states:

> While PO purports to rely upon the figures in the '751 Patent to support this construction (*id.*), the figures actually illustrate a plate that would not satisfy PO's proposal because, like a person's hand, the '751 Patent's cross-joint hole (green) is actually *below* the planar space between the first and second holes (blue).

Reply 8.

Mr. Leinsing's deposition testimony discussed above relates to a discussion of Figures 1 and 2 in Arnould. *See* Ex. 1015, 149:19–153:12. Figure 2 of Arnould is set forth below.

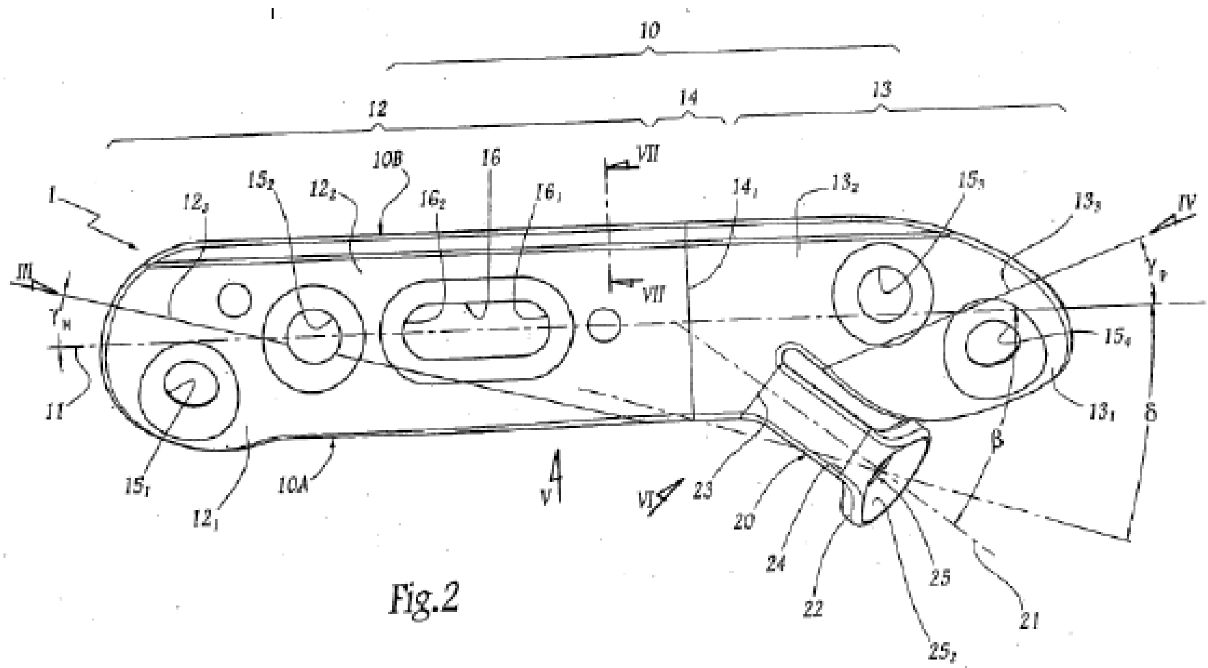


Fig.2

Ex. 1006, Fig. 2.

Concerning Figure 2 shown above, Mr. Leinsing testifies that hole 25 would not be "between" the holes at the two opposite ends of the bone plate as shown above, which are delineated in Figure 2 as $15_{1\text{-}4}$, and in Figure 1 as 3 and 4. Ex. 1015, 151:8–13; Ex. 1006 ¶ 21, Fig. 1. Mr. Leinsing testifies that hole 25 is "in a different plane, and it's offset and its axis to the hole is not in any relation to the main part of the Arnould plate." Ex. 1015, 151:18–20. When asked whether, if leg 20 were bent to be in the same plane as the bone plate, that would make hole 25 between holes 3 and 4, Mr. Leinsing answered no. *Id.* at 151:21–152:2. Mr. Leinsing explained "[b]ecause it wouldn't be between those holes. It wouldn't lie in the space between the holes or the screws shown in 4 and 3" as he defines "between" as "at, into, or across the space separating two objects, places, or points." *Id.* at 151:21–152:17. To be "between" as he defines it, Mr. Leinsing testifies that hole 25 "would need to be on that main body of the Arnould plate and then have the

other requirements as required by the claims." *Id*. at 152:18–25.

We do not agree that the ordinary meaning of "between" is as restrictive as Patent Owner contends. First, Patent Owner's definition of "between" does not require an object that is "between" two others to lie along the same axis defined by the two other objects. A "space separating two objects" is not so restrictive. Instead, a more expansive ordinary meaning of "between" is evidenced by the intrinsic evidence of the '751 patent as Petitioner explained with reference to Figure 2 of the '751 patent, which shows a third hole 1a1 between the other holes even though it is "offset" and in a different plane from the longitudinal axis of the bone plate.

Patent Owner attempts to draw a distinction between Arnould's Figure 2 and Figure 2 of the '751 patent, by asserting "like Arnould, a hand is in a different plane *and* offset *and* its axis is not in relation to the body. In contrast, the angled tab shown in Figure 2 of the '751 patent is *not* in a different plane *and* offset from the plate, and the hole axis forms an angle with the plate." Sur-reply 8. Patent Owner's distinction here appears to be whether the third hole lies at an angle below or above the bone plate as shown in Figure 2 of the '751 patent (which would be "between" according to Patent Owner) versus also being positioned to either side of the bone plate as shown in Figure 2 of Arnould (which in Patent Owner's view would mean that hole is no longer "between" the others). We see no basis for drawing such a fine distinction regarding the meaning of "between," especially when the narrower definition Patent Owner seeks is not made explicit in the Specification of the '751 patent.

To the extent any further claim construction is necessary to resolve the issues presented in this proceeding, we consider such in our analysis below.

D. Overview of Arnould, Zahiri, and Myerson

i. Arnould (Ex. 1006)

Arnould is a European patent filed September 10, 2007 and published on March 12, 2008. Ex. 1006, codes (22), (43). Petitioner asserts, and Patent Owner does not dispute, that Arnould qualifies as prior art under 35 U.S.C. § 102(b). Pet. 8.

Arnould describes "an arthrodesis plate for a metatarsal-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe" and "a surgical method for placing such an arthrodesis plate." Ex. 1006 ¶ 1.

Figure 1 of Arnould, reproduced below, "depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." Ex. 1006 ¶ 11.

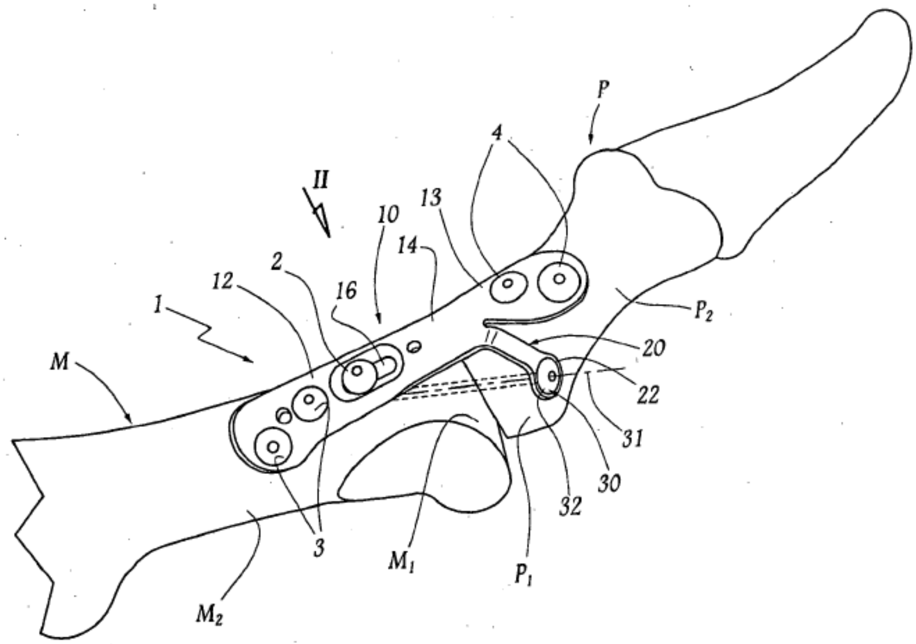


Fig. 1

Figure 1 above shows screws 2 and 3 extending through holes 15_1 and 15_2 in plate 1 to "secure the plate body 10 to the metatarsal M."[6] *Id.* ¶ 33. "Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P." *Id.* ¶ 34. Screw 30 is inserted through hole 25 "following a direction of insertion inclined in relation to the plate body 10 at an angle . . . chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1" to join those bones. *Id.* ¶ 32; *see also id.* ¶ 6 (explaining that this screw "will extend both through the bone material of the phalanx and into the bone material of the metatarsal").

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[6] The labels for holes 15_1, 15_2, 15_3, 15_4, and 25 do not appear in Figure 1 of Arnould, but are shown in other figures depicting Arnould's plate. *See, e.g.*, Ex. 1006, Figs. 2, 4.

Arnould also teaches that "in order to allow the screw 30 to be screwed in and locked with its axis 31 inclined in relation to the central axis" of hole 25, that hole has "a concave surface which is substantially complementary to an associated surface delimited by this screw head." Ex. 1006 ¶ 27. Figure 4 of Arnould is reproduced below and provides an elevation view of plate 1 from another angle.

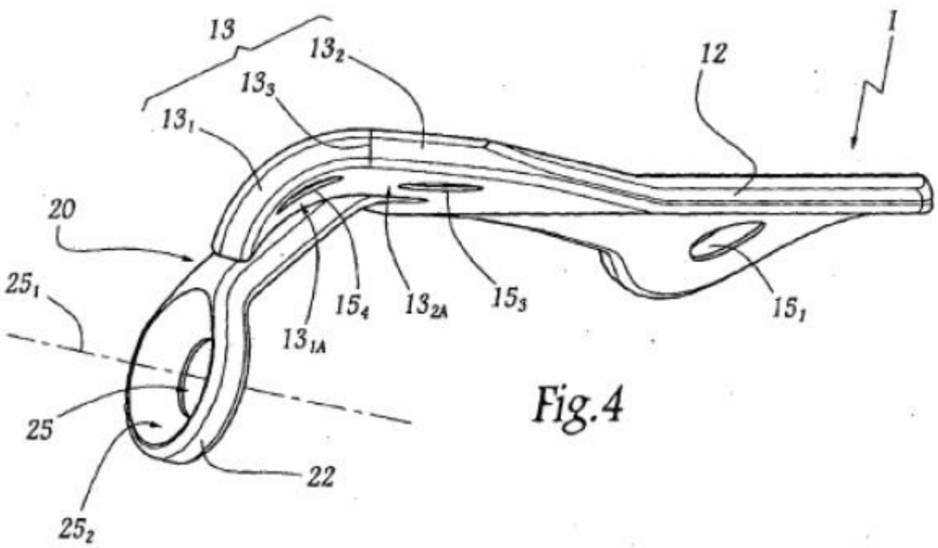


Fig.4

Figure 4 above shows hole 25 with a concave edge 25_2. *Id.* ¶ 27. According to Arnould, "when screw 31 is fully inserted into the hole 25, its head 32 comes to rest and wedge[s] against at least a portion of the edge 25_2." *Id.*

ii. Zahiri (Ex. 1007)

Zahiri is a United States patent filed on September 26, 2006, and issued May 29, 2012. Ex. 1007, codes (22), (45). Petitioner asserts, and Patent Owner does not dispute, that Zahiri qualifies as prior art under 35 U.S.C. § 102(e). Pet. 9.

Zahiri describes "fixation devices for compressing bone fractures of a human being." Ex. 1007, 1:9–11. Figure 1 of Zahiri, reproduced below from

the version on page 11 of the Petition, depicts an embodiment of Zahiri's fixation device.

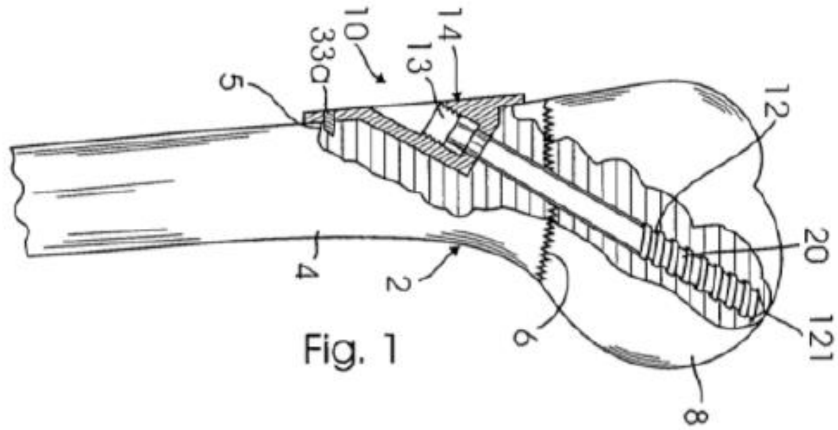


Fig. 1

Figure 1 of Zahiri shows the insertion of lag screw 12 through guide plate 14 such that it extends through fracture line 6 in the bone at "an angle of 150 degrees or 170 degrees." *See id.* at 4:58–67. According to Zahiri, the inclined angle of the "short barrel portion" of the guide plate can vary in "the range of from 90 to 170 degrees." *Id.* at 3:59–67.

Zahiri also teaches that the plate may include holes for pins "designed to temporarily lock" the plate in position "so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." Ex. 1007, 3:11–18; *see also id.*, Fig. 8 (holes 235a-d).

iii. Myerson (Ex. 1010)

Myerson is a United States patent application published on October 26, 2006. Ex. 1010, code (43). Petitioner asserts, and Patent Owner does not dispute, that Myerson qualifies as prior art under 35 U.S.C. § 102(b). Pet. 10.

Myerson describes "[a] fixation plate for use in fusion of the metatarsal-phalangeal joint" with a number of screw holes. Ex. 1010, code

(57). Myerson discloses an embodiment in which at least some of these "screw holes are designed to receive locking screws, such as by the incorporation of locking screws . . . within the screw hole." *Id.* ¶ 22. According to Myerson, "[t]he locking threads can be of a variety of known configurations as dictated by the particular cortical locking screw." *Id.*

E. Ground 4: Obviousness over Arnould and Zahiri

Petitioner contends claims 1–3 and 7–18 would have been obvious over Arnould and Zahiri. *See* Pet. 62–89. As explained below, Petitioner has shown by a preponderance of the evidence that these claims would have been obvious over Arnould and Zahiri.

i. Independent Claims 1, 11, and 17

1. Claim 1

Petitioner contends that Arnould teaches or reasonably suggests the elements of the recited combination, including a bone plate with first and second ends and with a length that defines a longitudinal axis, and that spans a first and second bone separated by a joint (i.e., plate body 10 that includes metatarsal portion 12 and phalangeal portion 13 along its longitudinal direction 11), a first hole at or adjacent a first end of the bone plate to align with the first bone (i.e., plate 1 having holes 15_3 and 15_4 aligned with the phalanx), a second hole at or adjacent a second end of the bone plate to align with the second bone (i.e., plate 1 having holes 15_1 and 15_2 aligned with the metatarsal), a third hole between the first and second hole that is angled relative to the longitudinal axis of the bone plate (i.e., hole 26 into which screw 30 is configured to be inserted at an angle δ selected by the surgeon), a first fixation member for insertion through the first hole and into the first

bone (i.e., screws 4 that are inserted in holes 15_3 and 15_4), a second fixation member for insertion through the second hole and into the second bone (i.e., screws 3 that are inserted in holes 15_1 and 15_2), and a third fixation member for insertion through the third hole into the first bone and into the second bone such that the free end of the third fixation member is not attached to any portion of the bone plate and resides in the second bone and the third fixation member is the only fixation member extending across the joint (i.e., screw 30 that is configured to pass through the phalangeal epiphysis and anchor to the metatarsal epiphysis). Pet. 67–77 (citing evidence). Petitioner relies on Zahiri as additional evidence for elements [1d] and [1h] and, based on the full trial record, has articulated a sufficient rationale for combining Zahiri's teachings regarding those limitations with Arnould to the extent they are not already taught in Arnould itself. Pet. 62–66, 70–72, 76–77 (citing evidence).

We find Petitioner's arguments and evidence persuasive. Arnould teaches a bone plate depicted in Arnould's figures for fusing a joint, e.g., the "metatarsal-phalangeal joint particularly . . . the joint between the first metatarsal and the first phalanx of the big toe" (limitation [1pre]). Ex. 1006 ¶ 1. As shown in Arnould Figure 1, reproduced below, bone plate 10 is positioned to span a joint between a first and second bone, specifically the phalanx P on the right and the metatarsal M, and has holes aligned with each of those bones adjacent to the ends of the bone plate (limitations [1a], [1b], and 1[c]).

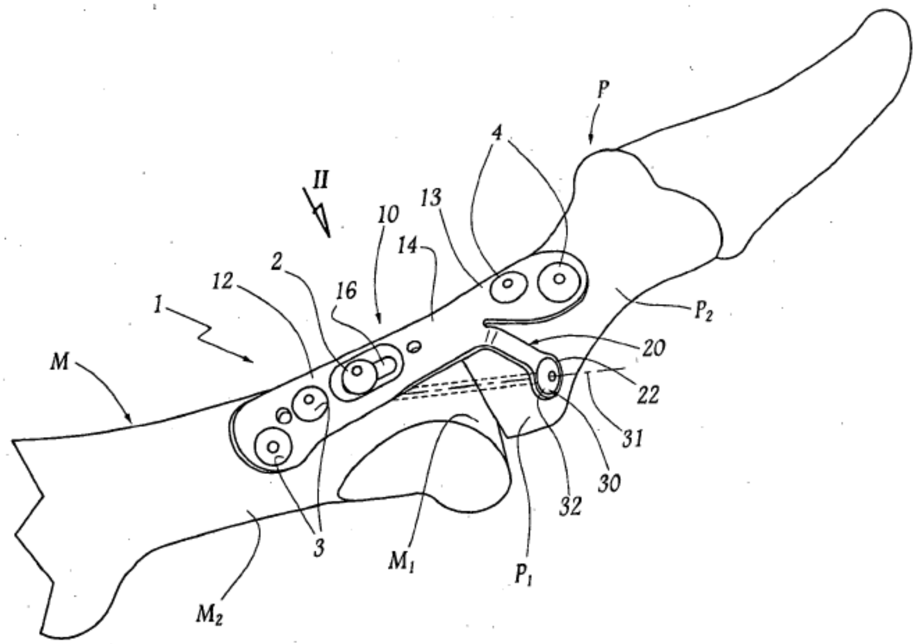
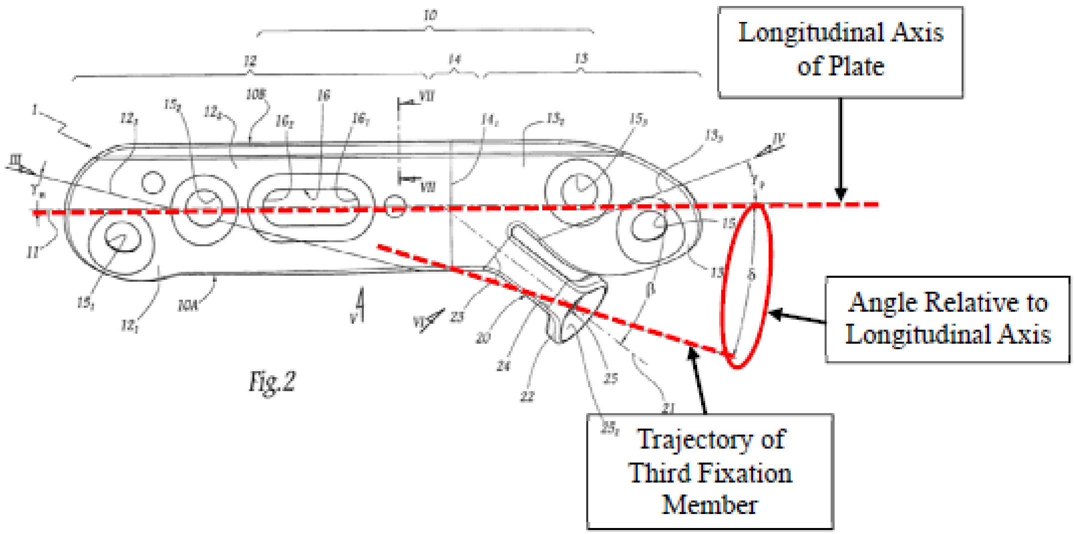


Fig. 1

As shown in the figure, screws 4 (i.e., "fixation member[s]" as recited in claims 1, 11, and 17) are inserted through holes in the plate 10 into the first bone P (limitation [1e]) and screws 3 are inserted through holes in the plate 10 into the second bone M (limitation [1f]). *Id.* ¶¶ 33–34. Screw 30 is inserted through a hole in plate 10 into the first and second bone such that the free end resides in the second bone and the head 32 of screw 30 resides in the hole (limitation [1g]). *Id.* ¶ 32. Moreover, as shown in Figure 1, screw 30 is the only fixation member that extends across the joint (limitation [1h]).

Arnould also teaches that the hole through which screw 30 extends is configured as recited in limitation [1d]. Figure 2 of Arnould, reproduced below, shows hole 25, which Petitioner maps to the "third hole" in claims 1, 11, and 17.



Pet. 70.

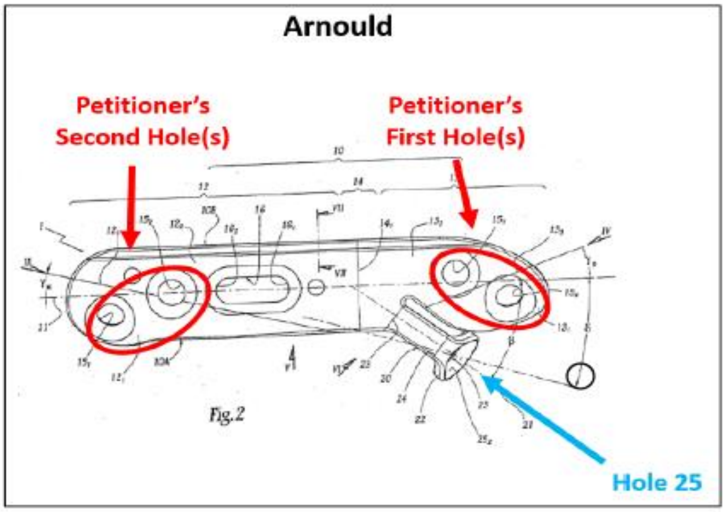
Petitioner adds red dotted lines demonstrating that the trajectory of the third fixation member (i.e., screw 30) through hole 25 is angled relative to the longitudinal axis of the plate (limitation [1d]). More specifically, as shown in Figure 2:

> The hole 25 is provided to receive the screw 30 so that, depending on the direction of observation corresponding to arrow II, the longitudinal axis 31 of this screw can be inclined in relation to the longitudinal direction 11 of the plate body 10, forming a non-zero angle δ with this direction 11. It can be understood that the smaller this angle δ is, the more the axis 31 of the screw 30 tends to align with an anteroposterior direction, guaranteeing a greater depth of penetration of the screw into the metatarsal for any given length of screw.

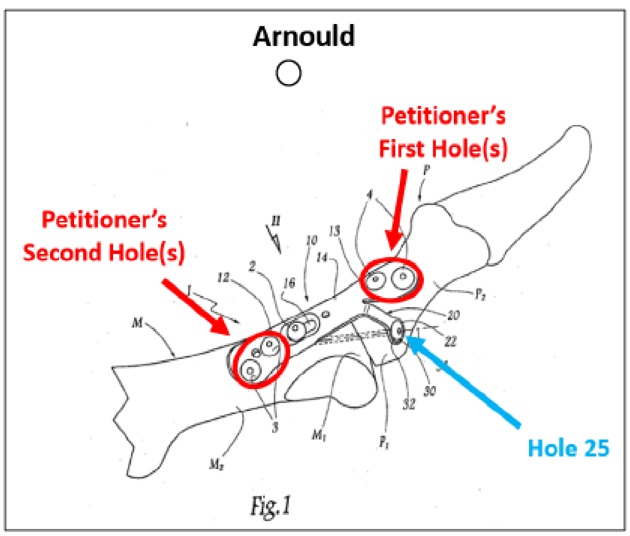
Ex. 1006 ¶ 27.

Patent Owner asserts that Petitioner does not explain sufficiently how Arnould discloses "a third hole located between said first hole and said second hole." Resp. 70–73. Patent Owner points to its definition of "between," as supported by Figure 1 of the '751 patent, as the third hole "located in the space separating the first hole and the second hole." *Id.* at

70–73. Patent Owner further illustrates why Arnould's plate would not satisfy its definition of "between." *Id*. Patent Owner's annotated Figures 1 and 2 of Arnould is set forth below.



Resp. 72.



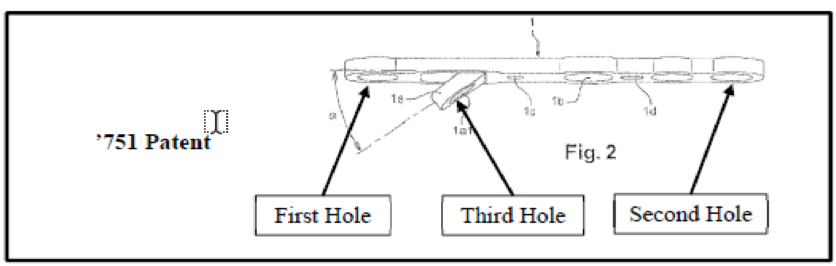
Resp. 73. Patent Owner annotated Figures 1 and 2 set forth above to show what Petitioner has asserted is the claimed first and second holes on Arnould's plate as well as hole 25 of Arnould's plate that Petitioner asserts is the claimed "third hole." Patent Owner argues:

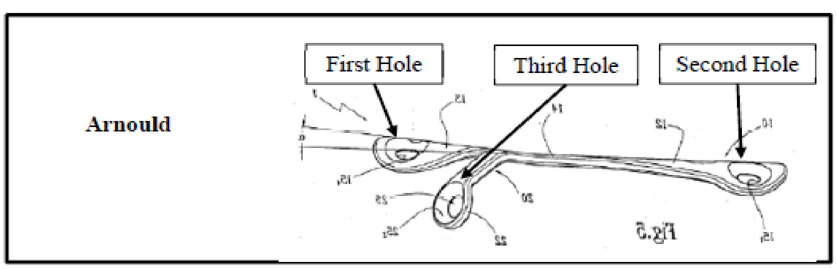
Hole 25 is located on leg 20, which "extends lengthwise from

> the phalangeal portion 13" and "gives the impression of *plunging downward* in relation to the plate body 10, so that its end 22, which is located *vertically below* this plate body in the configuration of implantation of the plate 1, is pressed against the inner lateral surface of the phalangeal epiphysis P1.

Resp. 71 (quoting Ex. 1006 ¶¶ 23, 26 (emphasis added by Patent Owner). Patent Owner concludes that "[a]s shown in annotated Figures 1 and 2, hole 25 of Arnould is not located in the space separating the 'first hole' and 'second hole' but is rather located below, off to the side of, and on a different plane as compared with the first and second holes." Resp. 73 (citing Ex. 2005 ¶¶ 266–269).

As we stated in our claim construction section, we do not agree that "between" is so limited. There is nothing in the ordinary meaning of "between" that would require the third hole to lie on the same axis between the first and second holes. Petitioner provides an apt illustration that the orientation of Arnould's "third hole" 25 is very similar to an embodiment in the '751 patent. Petitioner's annotated comparative figures are set forth below.





Reply 29 (annotated by Petitioner; Figure 5 of Arnould is reversed). Figure 2 from the '751 patent and Figure 5 from Arnould shown above depict bone plates with first, second, and third holes.

Petitioner concludes that "[i]n both figures, the third hole is between the first and second holes, even though both are below the main body of the plate." Reply 30. We agree. We determine that both the third holes shown in Figure 2 of the '751 patent and in Arnould's Figure 5 shown above are "between" the first and second holes.[7]

Patent Owner also contends that Arnould does not teach or suggest limitation [1d] because "while the trajectory of screw 30 may be angled, it does not follow that hole 25 is necessarily angled." Resp. 74. With reference to Figures 2, 4, and 6 of Arnould, Patent Owner states:

> [H]ole 25 is not an "angled hole" as claimed. Rather, hole 25 appears to have the same shape and geometry of holes 15_1, 15_2, 15_3, and 15_4, none of which are angled through the bone plate. Hole 25 includes "a concave surface which is substantially complementary to an associated surface delimited by this screw head." Arnould does not say that hole 25 is itself angled relative to the longitudinal axis of the plate.

Resp. 74 (citing Ex. 1006, Figs. 2, 4, 6, ¶ 27; Ex. 2005 ¶¶ 272–273).

We disagree with Patent Owner. The claim does not require that the third hole be at any particular angle, nor does it require that the hole limit the

[7] Patent Owner asserts that the Petition does not sufficiently address limitation [1d] of the challenged claims, and cannot do so on reply. Sur-reply 30 n.8, 31. We do not agree. In the Petition, Petitioner identifies hole 25 as the claimed "third hole" and provides annotated Figure 2 of Arnould showing hole 25 is between the claimed first and second holes. *See* Pet. 69–70. Petitioner's argument in its Reply responds to Patent Owner's questioning of the ordinary meaning of "between," and is appropriate rebuttal argument.

trajectory of the third fixation member to a particular angle relative to the longitudinal axis. All that is required is that the third hole be "angled relative to the longitudinal axis of said bone plate." Ex. 1001, 3:20–21. Such a configuration is unequivocally shown in Arnould's figures. Figure 2 of Arnould shows that hole 25 is disposed at an angle to the longitudinal axis 11 of the plate.[8] Arnould explains that angle δ in Figure 2 is the angle of axis 31 (labeled in Figure 1) of screw 30 relative to the longitudinal axis 11 of the plate. Ex. 1006 ¶ 27. Arnould teaches that the concave surface of hole 25 "is substantially complementary to an associated surface delimited by" the head of screw 30 such that when the screw "is fully inserted into the hole 25, its head 32 comes to rest and wedge[s] against at least a portion of the edge 25_2, even if its axis 31 is inclined in relation to the axis 25_1 of the hole." Ex. 1006 ¶ 27. Thus, Arnould teaches that the axis 25_1 of hole 25 (labeled in Figure 4) may be "inclined in relation" to the axis of the screw or it may not be—in which case the axis of screw 30 and the axis of hole 25 would be at the same angle, i.e., angle δ, to the longitudinal axis 11 of the plate. *Id.* In either event, the axis of Arnould's third hole is angled relative to the longitudinal axis of the bone plate, as recited in limitation [1d].

Arnould additionally discloses this limitation because the inner surface of hole 25 is angled relative to the longitudinal axis of the plate. As shown in Figure 4 of Arnould, the diameter of hole 25 on the outer surface of the plate is larger than the dimeter of the hole on the inner surface,

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[8] Figure 2 depicts angle β, which is described as the angle of the leg 20 relative to the longitudinal direction of the plate body, and angle δ, which is described as the angle of the longitudinal axis of screw 30 to the plate body. Ex. 1006 ¶¶ 25, 27.

resulting in a "concave surface" on the interior of hole 25. *See, e.g.*, Ex. 1006, Fig. 4, ¶ 27. As shown in Figure 4, this concave surface is "angled relative to a longitudinal axis of said bone plate" as recited in limitation [1d].

The testimony Patent Owner cites from Mr. Leinsing does not show otherwise. Mr. Leinsing's testimony appears to be premised on limitations not recited in the claim itself. *See* Ex. 2005 ¶¶ 188–89 (asserting that "[a]ngle β [in Arnould Fig. 2] is formed by the longitudinal direction 11 and longitudinal direction 21 of leg 20, not hole 25" and that "hole 25 is not an 'angled hole' as claimed"). Neither Patent Owner nor Mr. Leinsing squarely addresses the fact that Arnould's figures show that both hole 25 and the concave inner surface of that hole are disposed at an angle to the longitudinal axis of the plate. *Id.* In contrast, Mr. Sherman's testimony is consistent with the figures and written description in Arnould. Ex. 1002 ¶¶ 263–64. Accordingly, we find Mr. Sherman's testimony on this point to be more credible than the competing testimony from Mr. Leinsing.

For these reasons, Petitioner has demonstrated that Arnould teaches or suggests all of the limitations of claim 1. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 1 would have been obvious over Arnould alone.

We also address Petitioner's alternative theory that claim 1 would have been obvious over the combination of Arnould and Zahiri.[9] For this

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[9] The Petition explains that the proposed combination of Arnould with Zahiri is an alternative basis for the unpatentability of claim 1, i.e., "[i]t may be argued that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate." Pet. 63; *see also* Reply 25 (explaining that Arnould meets the requirements of claim 1

theory, Petitioner relies on Zahiri as additional evidence that a third hole configured as recited in limitations [1d] and [1h] would have been obvious. *See* Pet. 63–64, 70–71, 76–77. Petitioner illustrates its contentions with Figures 4 and 8 of Zahiri. We begin with Figure 4 as annotated by Petitioner that is reproduced below.

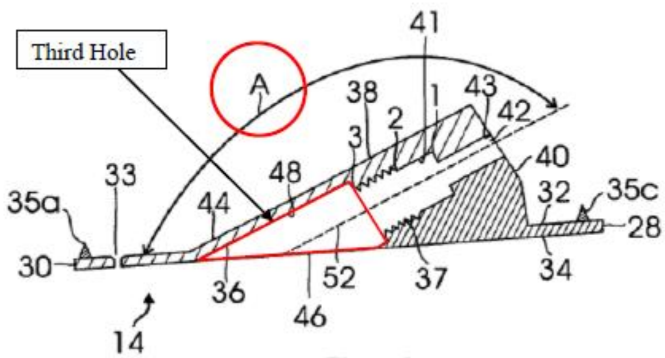

Fig. 4

Pet. 71. Petitioner annotates Figure 4 above to identify what it calls Zahiri's "third hole," the configuration of which in Zahiri's plate teaches limitation [1d]. Petitioner states: "Zahiri's bone plate comprises a barrel portion 38 with a third hole defined by an inner side wall 48 that extends from an opening 46 and a third point 3. The third hole is angle[d] at an incline "'A' relative to the central longitudinal line of the plate." *id*. (citing Ex. 1007, Fig. 4 (annotated); 6:12–35, 6:50–56.

Petitioner annotates Figure 8 of Zahiri set forth below.

"without turning to the disclosure of Zahiri, rendering [Patent Owner's] combination challenges irrelevant").

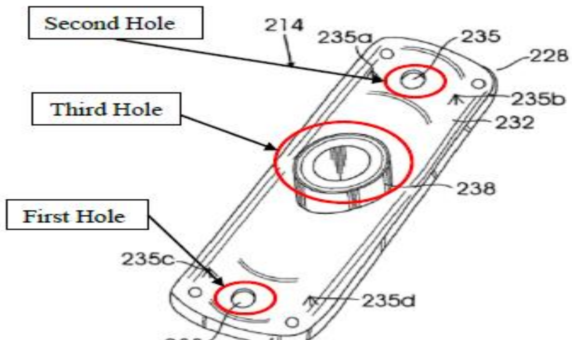

Fig. 8

Petitioner offers Figure 8 above as showing that "Zahiri further shows the barrel portion 238 (third hole) located between the first hole 233 and the second hole 235." Pet. 71. Petitioner also urges that "a POSITA would have looked to Zahiri for a way to improve the integrity of the angled fixation screw." Pet. 76 (citing Ex. 1002 ¶ 280). Petitioner points to Figure 1 of Zahiri depicted below to illustrate this point.

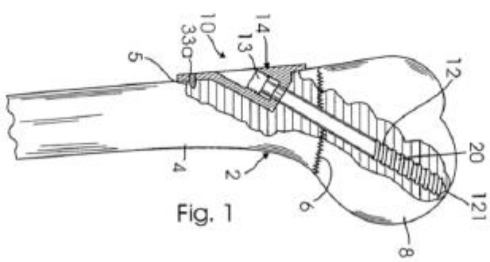
Fig. 1

Pet. 77. With reference to Figure 1, Petitioner asserts that "Zahiri depicts a bone plate comprising a guide hole through a barrel portion configured to angle a lag screw through a first bone and into a second bone. (Ex. 1007, 2:23–36). Zahiri shows that the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone and the second bone (Ex. 1007, Fig. 1; 2:23–36)," which teaches limitation [1h]. Pet. 76–77.

Petitioner contends that "[a] POSITA would have looked to Zahiri when making improvements to the plate disclosed in Arnould" because "Arnould's disclosure at least guides a POSITA to incorporate the teachings

of Zahiri, and position the third hole at an angle relative to the longitudinal thickness of the bone plate." Pet. 63–64 (citing Ex. 1002 ¶¶ 248–249). In other words, Petitioner proposes modifying hole 25 in Arnould's plate to incorporate the angled hole with a seated screw head configuration depicted in in Figure 1 of Zahiri (referred to hereinafter as "Zahiri's angled hole configuration"). *See id.* at 70–71, 76–77. According to Petitioner, a POSITA would have been motivated to make this combination because Zahiri teaches that this arrangement "allows a sufficient amount of force to be applied between two bone while dissipating the force along the plate so it does not damage the bones," and a POSITA would have known that "bone plates configured for arthrodesis [like those taught in Arnould] and bone plates configured to fuse bone fractures [like those taught in Zahiri] have been used interchangeably for decades." *Id.* at 63–64 (citing Ex. 1007, 5:65–6:11; Ex. 1002 ¶ 249).

We again find Petitioner's arguments and evidence persuasive. Figure 1 of Zahiri shows "plate 14" having an angled hole extending through the thickness of the device with a screw inserted to join two bone parts wherein the free end of the single screw resides in the second part and is not attached to the plate. Ex. 1007, Fig. 1, 4:58–67. The hole for the screw is between the first and second holes, 233 and 235, as shown in Figure 8 and recited in limitation [1d], the third hole is disposed at an angle relative to the longitudinal axis of the device as recited in limitation [1d], and Zahiri's bone plate is configured for only a single lag screw to be extend from one side of the joint to the other as shown in Figure 1 and as recited in limitation [1h]. Zahiri teaches that this configuration is desirable because it dissipates compression forces, which avoids "failure by loosening of the device" and

keeps the bone cortex "healthy and intact." *Id.* at 5:65–6:7. Moreover, Mr. Sherman provides testimony, which we credit, explaining that "bone plates configured for arthrodesis and bone plates configured to fuse bone fractures [like Zahiri's plate] have been used interchangeably for decades." Ex. 1002 ¶ 249. Thus, even if Arnould did not itself teach or suggest a third hole configured as recited in limitations [1d] and [1h], Petitioner has shown that its proposed combination of Arnould and Zahiri does and articulated reasoning with rationale underpinning demonstrating that a POSITA would have been motivated to make that combination with a reasonable expectation of success.

Patent Owner contends that Zahiri is not analogous art to the '751 patent and therefore cannot be combined with Arnould because Zahiri "discloses only a 'guide plate'" and not "a 'bone plate,' as properly defined." Resp. 25, 60–61. According to Patent Owner, Zahiri's plate is not a "bone plate" because it "is designed to be positioned on only one side of a fracture – it does not span any fracture, let alone a joint." *Id.* at 25; *see also* Sur-reply 17 (arguing that "under the proper construction of 'bone plate' . . . Zahiri is *not* a 'bone plate'"). Moreover, Patent Owner contends that "[t]he Zahiri device does not itself serve as structural support to immobilize the bone segments" and is designed for a "specific procedure." *See id.* at 26.

We disagree with Patent Owner for several reasons. First, the narrow construction of "bone plate" that Patent Owner proposes to distinguish Zahiri is not supported by the record. *See supra* § III.C.i. We agree with Petitioner that the ordinary meaning of "bone plate" includes plates like those described in Zahiri. *Id.* Second, even if Patent Owner's construction were correct, the scope of analogous art is broader than Patent Owner

contends. A reference is considered to be analogous art if it is in the "same field of endeavor" as the patent at issue. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Here, the Specification states that "[t]he invention relates to the technical field of orthopedic implants." Ex. 1001, 1:27–28. Zahiri falls squarely within this field, describing "fixation devices for compressing bone fractures of a human being." Ex. 1007, 1:9–11; *see also, e.g.*, *id.* at Fig. 1 (depicting the use of Zahiri's plate as an orthopedic implant to fix two bone parts). The differences Patent Owner identifies in Zahiri's device do not show otherwise.

In this regard, we find the testimony of Mr. Sherman (Ex. 1002 ¶ 245) on this point to be more credible than the competing testimony offered by Mr. Leinsing (*see* Ex. 2005 ¶¶ 121–29, 238). Mr. Sherman persuasively testifies that "Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone," demonstrating Arnould and Zahiri "are therefore in analogous fields of invention" to the '751 patent. Ex. 1002 ¶ 245. Mr. Leinsing, on the other hand, continues to assert that Zahiri discloses only "a guide that directs a lag screw at a precise angle into a humeral head, not a bone plate" because it is located on only one side of the joint or fracture. Ex. 2005 ¶ 238. Therefore, Mr. Leinsing concludes that the "Zahiri device is directed to a completely different function than Arnould," and is non-analogous art. *Id*. Because we find Zahiri discloses a "bone plate" according to the ordinary meaning of that term, Mr. Leinsing's testimony is unconvincing. *See supra* § III.C.i (explaining that the ordinary meaning of "bone plate" does not exclude plates located on only one side of a joint or fracture). But even if we agreed with Patent Owner's and Mr. Leinsing's interpretation of bone plate,

Zahiri's plate is still an orthopedic implant and therefore analogous art because it is within the same field of endeavor as the '751 patent.

Patent Owner's argument that Zahiri teaches away from a combination with Arnould is also unavailing. *See* Resp. 61–67. Patent Owner asserts that unlike Arnould's plate, Zahiri's "is specifically designed to prevent a surgeon from having the flexibility to select a different screw trajectory than that dictated by the shape of the barrel," *see* Resp. 65 (citing Ex. 2005 ¶ 247), and thus, if combined with Arnould, "a surgeon would not be able to choose from among the multiple screw trajectories afforded by hole 25, defeating one of the main advantages of the Arnould plate," *see id.* (citing Ex. 2009, 904–91:9); *see also* Resp. 65 (stating "structural features that confine the head of Zahiri's lag screw . . . are incompatible with the Arnould plate" with the concave surface for the edge of third hole 25). But those distinctions do not rise to the level of a teaching away. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009)) ("A reference does not teach away . . . if it . . . does not criticize, discredit, or otherwise discourage investigation into the invention claimed."). Moreover, Petitioner's combination is premised on modifying hole 25 in Arnould's plate to have Zahiri's angled holed configuration. That combination would retain Arnould's flexible plate, while fixing or at least limiting the angle of screw 30 through the hole. However, Petitioner explains that "Zahiri discloses providing plates with a variety of angles in a kit so the surgeon can choose the plate that will maximize fixation based on the particular needs of the patient." Reply 22; *see also* Ex. 1007, 3:59–64, 9:1–4 (teaching that the hole may configured in a range of angles to

accommodate the device's use "for a variety of fractures, fusion procedures and osteotomies"). Thus, a POSITA could compensate for the fixed angle and, in any event, the fact that one embodiment may be preferable in some instances does not teach away from the proposed combination. *See UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023) (explaining that a teaching that one composition is "optimal or standard" or that expresses a "preference" for something does not teach away from other options) (internal quotations omitted).

Patent Owner's remaining arguments against the combination of Arnould and Zahiri are also unavailing. Patent Owner contends that there would have been no reasonable expectation of success because "fusing an MTP joint with Arnould's bone plate is fundamentally different than using Zahiri's device to guide the position of a lag screw across a proximal humeral fracture at a fixed angle." Resp. 69 (citing Ex. 2005 ¶¶ 256–258); *see also* Resp. 66–67 (stating "Petitioner fails to discuss how the dimensions of Zahiri's odd angle internal fixation device 'for use in a transverse fracture of a humerus' would be modified for a plate that is placed 'on the upper surfaces of the metatarsal and phalanx connected by the joint."). The problem with Patent Owner's argument is that it assumes the bodily incorporation of the barrel portion of Zahiri's plate with Arnould's without consideration of a POSITA's exercise of ordinary skill to apply Zahiri's teachings to Arnould's bone plate. It is well-established, however, that a POSITA is understood to exercise "ordinary creativity" and is "not an automaton." *See KSR*, 550 U.S. at 421. Indeed, as our reviewing court recently observed, "a skilled artisan may be motivated to combine particular features of different references, e.g., to secure some benefits at the expense

of others, even when bodily incorporation would be impossible or inadvisable." *Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950, 957 (Fed. Cir. 2023).

This is the case here where Petitioner is proposing a relatively minor change to Arnould's plate, i.e., modifying the existing hole 25 in Arnould's plate to incorporate Zahiri's angled hole configuration.[10] There is no indication this configuration would not work if adapted to and sized for the dimensions of Arnould's plate and the anatomy of the metatarsal-phalangeal joint through the exercise of a POSITA's ordinary creativity. Indeed, Mr. Sherman offers testimony, which we credit, demonstrating that plates for fusing fractures and joints were known to be interchangeable. *See* Ex. 1002 ¶ 134. We find that evidence sufficient under the facts of this case

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[10] Patent Owner also asserts that Petitioner improperly relies on different embodiments of Zahiri set forth in Figures 4 and 8 to teach "said third hole is angled," without providing a motivation to combine these different embodiments with a reasonable expectation of success. *See* Resp. 76. We disagree and find that Petitioner is relying on the principles taught by Zahiri, including the configuration of the third hole, as applied to the Arnould plate. Zahiri itself provides this reasoning for applying the principles taught by the various embodiments of Zahiri. Although depicted in separate figures, Zahiri does not describe the principles illustrated in these figures as separate embodiments. To the contrary, Zahiri explains that the principles illustrated in its figures can be applied in many possible embodiments. *See* Ex. 1007, 4:48–53 ("Although specific embodiments of the present invention will now be described with reference to the drawings, it should be understood that such embodiments are by way of example only and merely illustrative of but a small number of the many possible specific embodiments which can represent application of the principles of the present invention."). Therefore, we determine that Mr. Sherman appropriately looks to different figures in Zahiri to glean principles related to Zahiri's angled third hole that may be applied to Arnould's plate.

to demonstrate that a POSITA would have had a reasonable expectation of success. Accordingly, Petitioner has shown by a preponderance of the evidence that claim 1 also would have been obvious over the combination of Arnould and Zahiri.

2. Claim 11

For ease of reference in discussing the limitations of claim 11, we set forth the full text of the claim below with bracketed annotations used in the Petition to identify particular limitations.

11. [11Pre] A system for fusing first and second bone parts, said system comprising:

[11a] a bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint, said bone plate having:

[11b] a first hole configured to align with the first bone part,

[11c] a second hole configured to align with the second bone part,

[11d] a third hole and a fourth located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the *third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area*, and

[11e] *a fifth hole located adjacent either the first hole or the second hole, said fifth hole being smaller in area than said first hole or said second hole*;

[11f] a first fixation member configured to be inserted through the first hole of said bone plate and into the first bone part;

[11g] a second fixation member configured to be inserted through the second hole of said bone plate and into the second bone

> part;
>
> [11h] a third fixation member configured to be inserted through the third and fourth hole in the bone plate, into the first bone part, across the fracture or joint, and into the second bone part, [11i] wherein a free end of said third fixation member does not attach to any portion of the bone plate and [11j] wherein the third fixation member is the only fixation member extending across the fracture or joint, *the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area*; and
>
> [11k] *a temporary fixation member configured to be inserted through the fifth hole in the bone plate*.

Ex. 1001, 3:61–4:29.

Claim 11 is similar to claim 1, and we have italicized claim language that is materially different from claim 1 requiring further analysis. We rely on our analysis for claim 1 above for the teachings in Arnould and/or Zahiri for a bone plate that spans or straddles a fracture or joint with a first hole for a first fixation member to be inserted into a first bone part, a second hole for a second fixation member to be inserted into a second bone part, and a third hole between the first and second holes for a single third fixation member to be inserted into the first bone part, across the fracture or joint into the second bone part with a free end not attached to the bone plate. *See supra* Section III.E.i.2. We discuss the remaining limitations of independent claim 11 below.

Concerning claim 11's requirement of a "third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area," Petitioner asserts that while "Arnould is silent regarding the dimensions of hole 25 . . . a POSITA would find that Zahiri discloses this element." Pet. 78 (citing Ex. 1007, Figs. 4, 8, 6:12–35,

8:34-44; Ex. 1002 ¶ 287). Petitioner provides an annotated Figure 4 from Zahiri to illustrate its point.

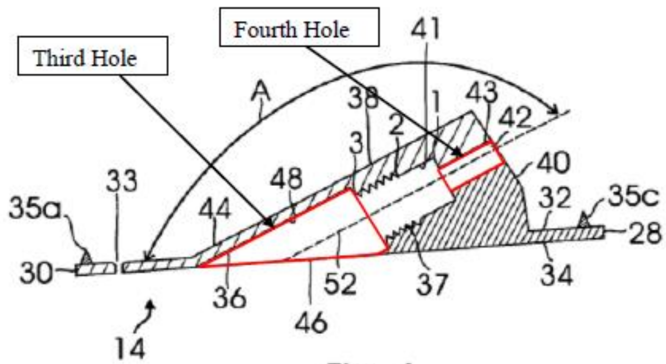

Fig. 4

Pet. 37. Petitioner describes annotated Figure 4 of Zahiri as follows.

> Zahiri's bone plate comprises a barrel portion 38 with a third hole defined by an inner side wall 48 extending from an opening 46 and a third point 3 and a fourth hole that is defined by an opening side wall 43 that extends from a first point 1 to an opening 42. The inner side wall 48 of the third hole has a larger diameter than opening side wall 43 of the fourth hole. A POSITA would understand that the area defined by the third hole is larger than the area defined by the fourth hole, as shown by annotated Figure 4. Looking to improve the integrity of the angled fixation screw of [Arnould], a POSITA would have readily looked to the disclosure of Zahiri.
>
> Additionally, the barrel portion of Zahiri's bone plate further discloses an axis, as shown by the dotted line in Figure 4. A POSITA would understand that the lag screw passes through the third hole and then through the fourth hole along the axis, as shown by Figure 4 above.

Pet. 36–37 (citing Ex. 1007, Fig. 4 (annotated); 6:12–35; Ex. 1002 ¶¶ 155–157).

We find Petitioner's arguments and evidence persuasive. Zahiri's Figure 4 set forth above as annotated by Petitioner shows a third and fourth hole outlined in red where the area defined by the fourth hole is smaller than

the area defined by the first hole as required by limitation [11d].

Patent Owner does not dispute that Zahiri teaches limitation [11d], but asserts that "a POSITA would not have been motivated to combine the alleged 'third hole and fourth hole' of Zahiri with Arnould." Resp. 77–78. We have addressed and rejected Patent Owner's argument that a POSITA would not be motivated to modify the existing hole 25 in Arnould's plate to incorporate Zahiri's angled hole configuration. *See supra* Section III.E.i.1.

Concerning claim 11's requirements of a "fifth hole" and a temporary fixation member to be inserted in the fifth hole reflected in limitations [11e] and [11k], Petitioner relies on the teachings of Zahiri. *See* Pet. 78–79. Specifically, Petitioner asserts that "Zahiri discloses four small holes 31a-d in the respective corners of the bone plate, located adjacent to medium size holes," which are used with temporary guide pins to hold the bone plate in place while a surgeon inserts the lag screw. Pet. 39 (citing Ex. 1007, Figs. 2, 8; 5:47–64); *see also id.* (annotating Figure 8 of Zahiri to identify "pin holes" in Zahiri's plate).[11]

We find Petitioner's arguments and evidence presented here persuasive. Zahiri's Figure 8 shows four holes that are smaller than the claimed first and second holes for use with temporary guide pins or temporary fixation members as required by limitations [11e] and [11k]. We also find persuasive Mr. Sherman's testimony that a POSITA would utilize the known technique of Zahiri for improving Arnould's plate "to guide the

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[11] Patent Owner asserts that Petitioner improperly combines different embodiments of Zahiri in Figures 2 and 8 without providing any reason why a POSITA would make such a combination. *See* Resp. 80. We have addressed this argument previously with respect to claim 1 as discussed above. *See supra* Section III.E.i.1. n.10.

plate alignment during implantation." Pet. 79 (citing Ex. 1002 ¶ 290).

Regarding Petitioner's argument that it would have been obvious to incorporate Zahiri's temporary guide pins and holes, Patent Owner argues that combination is "based on impermissible hindsight." Resp. 67–68. According to Patent Owner, "Arnould's plate is not at risk for unwanted torqueing or spinning like Zahiri's guide plate because Arnould's plate is (1) contoured to the metatarsal and phalanx, with a leg designed to wrap around the phalangeal epiphysis, and (2) 'partially immobilized' by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M." Resp. 68 (citing Ex. 1006 ¶ 31; Ex. 2007 ¶¶ 65, 44–45). For these reasons, Patent Owner contends that "proper alignment and temporary fixation is obtained in Arnould ***without*** the need for 'temporary guide pins used with pin holes' of Zahiri." *Id.* at 68 (citing Ex. 2007 ¶¶ 44–45, 63–66; Ex. 2005 ¶¶ 253–255).

In Reply, Petitioner points out that Patent Owner does not dispute that Arnould itself discloses pin holes as recited in claim 11. Reply 31 (citing Pet. 64). Petitioner urges that "[f]or additional details regarding these pin holes, a POSITA would be directed to Zahiri." *Id.*

In its Sur-reply, Patent Owner asserts that to the extent Petitioner is attempting to shift to a new argument that Arnould alone teaches these limitations, Petitioner has conceded that Arnould does not. Sur-reply 33 (citing Pet. 78–82, 75).

We find Petitioner's arguments and evidence persuasive. We find that it would have been obvious to incorporate Zahiri's temporary fixation pins for use with Arnould's plate especially in light of Arnould's depiction in

Figure 2 of temporary guide holes that may be used to temporarily secure the plate. *See* Ex. 1002 ¶ 251. Zahiri discloses the use of pins inserted through holes in the plate to temporarily fix the plate to the bone before the permanent screws are inserted. Ex. 1007, 3:10–18. Zahiri also teaches that those pins are removed after the screws are inserted. *Id.* at 7:63–66. We agree with Mr. Sherman's testimony that a POSITA would be motivated to combine the teachings of Arnould and Zahiri, to utilize a known technique for improving the implantation of a bone plate (similar device), and obtain an improvement to Arnould's bone plate to guide the plate alignment during implantation." *See* Ex. 1002 ¶ 290.

Patent Owner's argument that there would have been no need for this combination because Arnould obtains proper placement via other mechanisms is unavailing. *See* Resp. 79–80. As an initial matter, Patent Owner's argument ignores the fact that Arnould's figures depict pin holes in the plate. *See* Ex. 1002 ¶¶ 251–252 (annotating Figure 2 of Arnould to identify the "pin holes"). If it were true, as Patent Owner asserts, that there is no need for temporary fixation pins given the configuration of Arnould's plate, then there would be no reason for those pin holes. Yet, those holes are clearly depicted in Arnould's figures, and Patent Owner offers no alternative explanation for their purpose. Moreover, the other mechanisms Patent Owner points to only provide for partial immobilization of the plate. *See* Ex. 1006 ¶ 31 (explaining that the plate is "partially immobilized using the oblong hole 16" and screw 2 "without tightening the screw head against the edge of the hole" so that the "plate body 10 remains displaceable in the direction 11 relative to the metatarsal M"); Ex. 2005 ¶¶ 253–255 (annotating hole 16 and screw 2 in Figure 1 of Arnould and explaining how this

mechanism "partially immobilize[s]" the plate body during surgery while allowing the plate to remain displaceable in direction 11); *see also* Ex. 2007 ¶¶ 45 (same). The fact that Arnould teaches that its plate is partially immobilized using hole 16 and screw 2 does not obviate the motivation to incorporate Zahiri's temporary fixation pins to further immobilize the plate, either before or after the insertion of screw 2, to ensure correct alignment. For these reasons, we find Mr. Sherman's testimony (Ex. 1002 ¶¶ 64–65 (describing pin holes in Zahiri), 251–256 (describing combination of Arnould and Zahiri as teaching the fifth hole limitations [11e] and [11k]) to be more credible then the competing testimony Patent Owner cites from Mr. Leinsing and Dr. Holmes (Ex. 2005 ¶ 285–287; Ex. 2007 ¶¶ 44–45, 63–66) as discussed above.

Lastly, Petitioner asserts that Zahiri teaches the italicized portion of limitation [11j]—the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area. Resp. 81. Specifically, Petitioner relies on Zahiri's teaching of a such a fixation member as shown in Figure 1 of Zahiri. Pet 44–45 (citing Ex. 1002 ¶¶ 179–182), 81.

We agree with Petitioner that Zahiri discloses such a fixation member with a fixation head area of the lag screw that meets this part of limitation [11j]. Patent Owner does not respond to Petitioner's showing here.

Accordingly, Petitioner has shown by a preponderance of the evidence that claim 11 is unpatentable as obvious over Arnould and Zahiri.

3. Claim 17

For ease of reference in discussing the limitations of claim 17, we set forth the full text of the claim below.

> 17. An orthopedic implant comprising:
>
> a bone plate having a proximal surface and an opposite distal bone contacting surface, said bone plate having length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint,
>
> said bone plate having a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw,
>
> a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw,
>
> a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate, and
>
> a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member.

Ex. 1001, 4:42–67.

Petitioner relies on Arnould's plate that comprises an outer longitudinal side 10B that faces outward and an inner longitudinal side 10B that presses against the surface of the bones as disclosing the claimed bone plate with a first, second, and third hole configured as claimed. Pet. 82–83.

Petitioner, relying an annotated version of Figure 1 of Arnould shown below, asserts Arnould discloses the third bone screw as claimed.

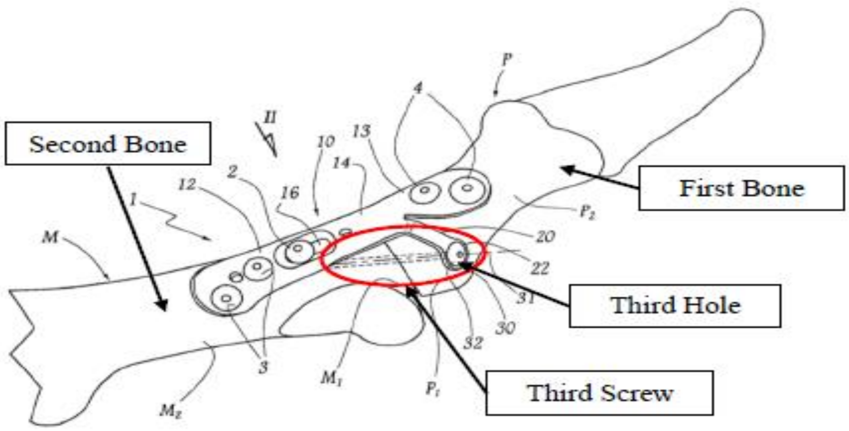

Fig.1

Pet. 84. Petitioner asserts that annotated Figure 1 shows:

> a screw hole 25 (third hole) configured such that the screw 30 (third bone screw) forms a non-zero angle in relation to the longitudinal direction of the plate body, and screw 30 passes through hole 25 and enters the phalanx and metatarsal bone. A POSITA would understand that screw 30 passes through the joint between the phalanx and the metatarsal.

Pet. 84–85.

Petitioner also asserts that while Arnould is silent regarding the dimensions of hole 25, a POSITA would look to Zahiri for the known dimensions of such openings to utilize "the seated head of the lag screw from Zahiri to ensure the third fixation member is seated securely in the third hole." *See* Pet. 85. Such teaching, Petitioner asserts, discloses the limitation "said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate." *Id*. Petitioner also relies on the combination of Zahiri and Arnould to teach the pin hole limitation of claim 17. *See* Pet. 85–86.

We have discussed above with reference to claims 1 and 11 how we

find Petitioner's arguments and evidence persuasive that the combination of the teachings of Arnould and Zahiri teach the claimed bone plate configuration with a first hole/first bone screw, second hole/second bone screw, third hole/third bone screw, and a pin hole as claimed in claim 17. *See* Sections III.E.i.1. and 2. Patent Owner does not present any additional arguments than those raised for claims 1 and 11 as to why the combination of the teachings of Arnould and Zahiri do not disclose the limitations of claim 17. We rely on our previous discussion of these arguments for claims 1 and 11.

Accordingly, Petitioner has shown by a preponderance of the evidence that claim 17 is unpatentable as obvious over Arnould and Zahiri.

ii. Dependent Claims 2, 3, 7–10, 12–16, and 18

Petitioner provides how the additional limitations of dependent claims 2, 3, 7–10, 12–16, and 18 are met by Arnould and/or Zahiri. *See* Pet. 86–89. We agree with Petitioner's assessment of how each of these additional limitations are met by the Arnould and Zahiri. *See id.*; Ex. 1002 ¶¶ 323–340.

Patent Owner responds with two arguments that we have previously addressed and rejected in the previous discussions above—namely, that a POSITA would not be motivated to combine Zahiri's temporary fixation features with Arnould's plate, and Petitioner has not sufficiently explained why a POSITA would be motivated to combine different embodiments of Zahiri. *See* Resp. 83.

Accordingly, Petitioner has shown by a preponderance of the evidence that claims 2, 3, 7–10, 12–16, and 18 are unpatentable as obvious over Arnould and Zahiri.

F. Ground 5: Obviousness over Arnould, Zahiri, and Myerson

Petitioner contends claim 6 would have been obvious over Arnould, Zahiri, and Myerson. *See* Pet. 90–91. Claim 6 depends from claim 1 and additionally recites "wherein said joint is a tarsometatarsal joint." Ex. 1001, 3:45–46. Petitioner relies on Myerson as it illustrates a bone plate fixed across the tarsometatasal joint as shown in Figure 1 of Myerson depicted below as annotated by Petitioner. Pet. 90–91.

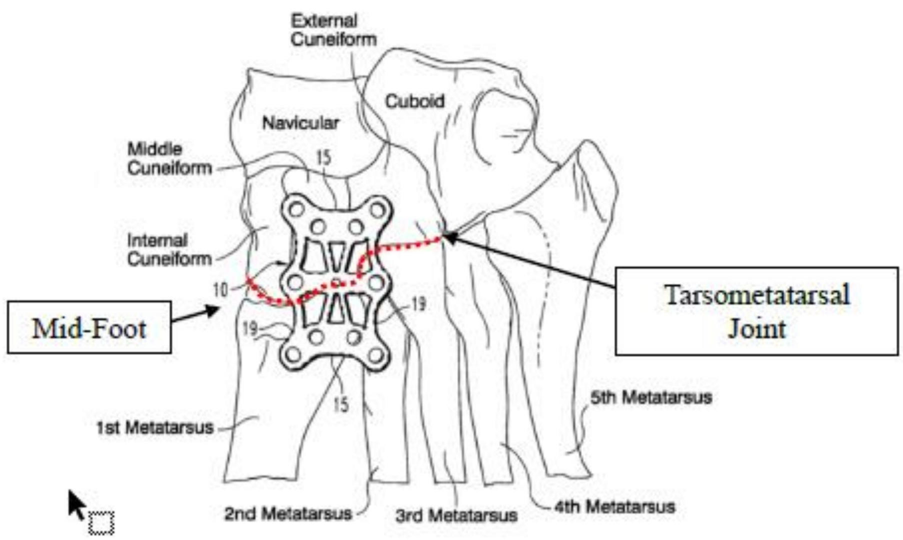

Fig. 1

Pet. 91. Petitioner asserts that "Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones 'anywhere along the mid-foot,' 'especially across the metatarsal joints,'" and Figure 1 above shows Myerson's bone plate fixed across the tarsometatarsal joint. *Id.* at 90; Ex. 1002 ¶ 345 (citing Ex. 1010 ¶¶ 21–22).

Mr. Sherman testifies that "a POSITA would understand that Myerson's bone plate is configured to fuse the tarsometatarsal joint," and "that Arnould's bone plate would easily be configured to contour to the

bones in the mid-foot and fuse the tarsometatarsal joint." Ex. 1002 ¶ 346. Mr. Sherman concludes that "[b]ased on Figure 1 of Myerson, and the specification cited above, Arnould in view of Zahiri and Myerson clearly discloses a system wherein said joint is a tarsometatarsal joint." *Id.* ¶ 347.

We find Petitioner's arguments and evidence persuasive. Myerson describes a bone plate for fusion of the "metatarso-phalangeal (MTP) joint," i.e., the same joint on which Arnould teaches its plate is used. Ex. 1010, code (57), Fig. 1, ¶¶ 1–2; Ex. 1002 ¶ 343 (stating "[i]n analogous art, Myerson discloses a bone plate for fusion of the MTP joint"). Myerson also teaches in the embodiment shown in Figure 1 above a bone plate for fusing the tarsometatarsal joint. Thus, Myerson teaches that similar bone plates can be used for both the MTP joint and the tarsometatarsal joint, which supports Mr. Sherman's testimony that a POSITA could easily configure Arnould's bone plant for the tarsometatarsal joint (Ex. 1002 ¶ 345) and evidences a motivation for doing so. For instance, Mr. Sherman testifies that "Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones 'anywhere along the mid-foot,' 'especially across the metatarsal joints,'" and Figure 1 shows Myerson's bone plate fixed across the tarsometatarsal joint." Ex. 1002 ¶ 345. Accordingly, Myerson teaches the additional limitations recited in claim 6 and Petitioner has articulated sufficient reasoning for combining those teachings with Arnould's plate.

Patent Owner attacks the combination of the teachings of Arnould, Zahiri, and Myerson by attacking each of the references separately. *See* Resp. 84–86. For instance, Patent Owner states that "the principles described in Arnould are specific to MTP joints and teach away from the modification of the plate for use with the TMT joint." Resp. 86 (citing Ex. 2005 ¶¶ 323–

329, 83–85). The test for obviousness, however, "is what the combined teachings of the references would have suggested to a person of ordinary skill in the art." *In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012).

Mr. Leinsing testifies that "[a] POSITA would understand that Arnould is configured solely for the metatarsophalangeal joint, and could not be used or configured to fuse the tarsometatarsal joint," and details the teachings of Arnould specific to the metatarsophalangeal joint. Ex. 2005 ¶¶ 327–328. Mr. Leinsing asserts that this amounts to a teaching away. *Id.* ¶ 328. Mr. Leinsing attempts to draw a negative inference for this teaching away in Arnould because the Specification of Arnould is directed to "an arthrodesis plate for a metatarsal-phalangeal joint, *particularly* for the joint between the first metatarsal and the first [proximal] phalanx of the big toe." *Id.* ¶ 327. Such a negative inference, however, does not rise to the level of a teaching away. *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009)) ("A reference does not teach away . . . if it . . . does not criticize, discredit, or otherwise discourage investigation into the invention claimed.").

As explained above, Petitioner has articulated sufficient reasoning with rationale underpinning for combining both Zahiri's angled hole configuration and Myerson's teaching of fusing the tarsometatarsal joint with Arnould's plate.

G. Grounds 1–3

Having determined that all of the challenged claims are unpatentable as obvious over the references in Grounds 4 and 5, we need not reach

Petitioner's argument that those same claims are also unpatentable as obvious over the references in the Grounds 1–3. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims"). Accordingly, we do not reach those grounds.

H. Patent Owner's Objections to Demonstratives

Patent Owner filed objections to certain demonstrative slides that Petitioner served for the oral hearing. *See* Paper 33, 1–2. Most, if not all, of Patent Owner's objections are moot because they relate to slides for grounds we do not reach in this decision. In any event, Petitioner's demonstratives are not evidence and we do not rely on them herein. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019), 84 (explaining that demonstratives are merely "aids to oral argument and not evidence" and therefore "the Board has not found that such objections are helpful in many cases"). Thus, we do not sustain Patent Owner's objections.

IV. CONCLUSION[12]

Petitioner has shown, by a preponderance of the evidence, that claims

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[12] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or*

1–3 and 6–18 of the ’751 patent are unpatentable.

Claim(s)	35 U.S.C. §	Reference(s)/ Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 2, 7, 8[13]	103	Slater		
1, 2, 7–18[14]	103	Slater, Zahiri		
6[15]	103	Slater, Zahiri, Myerson		
1–3, 7–18	103	Arnould, Zahiri	1–3, 7–18	
6	103	Arnould, Zahiri, Myerson	6	
Overall Outcome			1–3, 6–18	

V. ORDER

Accordingly, it is:

ORDERED that Petitioner has shown that claims 1–3 and 6–18 of U.S. Patent 10,993,751 B1 are unpatentable;

FURTHER ORDERED that Patent Owner’s objections to Petitioner’s

Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), 42.8(b)(2).

[13] As explained above, we do not reach this ground. *See supra* § III.G.
[14] As explained above, we do not reach this ground. *See supra* § III.G.
[15] As explained above, we do not reach this ground. *See supra* § III.G.

Demonstrative Slides (Paper 33) are overruled; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Jason Engel
Katherine Allor
K&L GATES LLP
jason.engel.ptab@klgates.com
katy.allor@klgates.com

For PATENT OWNER:

Sharon Hwang
Robert Surrette
Scott McBirde
MCANDREWS, HELD & MALLOY, LTD.
shwang@mcandrews-ip.com
bsurrette@mcandrews-ip.com
smcbride@mcandrews-ip.com

US009078713B2

(12) **United States Patent**
Prandi et al.

(10) **Patent No.: US 9,078,713 B2**
(45) **Date of Patent: *Jul. 14, 2015**

(54) **ORTHOPEDIC IMPLANT IN THE FORM OF A PLATE TO BE FIXED BETWEEN TWO BONE PARTS**

(71) Applicant: **MEMOMETAL TECHNOLOGIES**, Bruz (FR)

(72) Inventors: **Bernard Prandi**, Rennes (FR); **Keith Wapner**, Philadelphia, PA (US); **Charles P. Wapner**, Media, PA (US); **Peter W. Wapner**, Media, PA (US)

(73) Assignee: **MEMOMETAL TECHNOLOGIES** (FR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 88 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/041,706**

(22) Filed: **Sep. 30, 2013**

(65) **Prior Publication Data**

US 2014/0052193 A1 Feb. 20, 2014

Related U.S. Application Data

(63) Continuation of application No. 12/918,071, filed as application No. PCT/FR2009/051879 on Oct. 2, 2009, now Pat. No. 8,556,946.

(30) **Foreign Application Priority Data**

Oct. 2, 2008 (FR) 08 56694

(51) **Int. Cl.**
A61B 17/80 (2006.01)
A61B 17/84 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/8061*** (2013.01); ***A61B 17/8004*** (2013.01); ***A61B 17/808*** (2013.01); ***A61B 17/8057*** (2013.01); ***A61B 17/846*** (2013.01); *A61B 17/809* (2013.01)

(58) **Field of Classification Search**
CPC .. A61B 17/80; A61B 17/808; A61B 17/8057; A61B 17/8061
USPC 606/60, 280–299, 300–331
See application file for complete search history.

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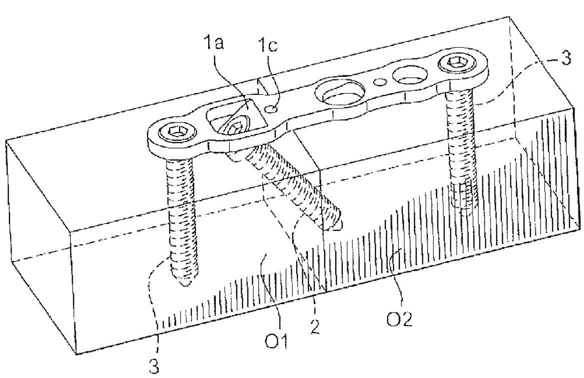
Primary Examiner — Christopher Beccia
(74) *Attorney, Agent, or Firm* — Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) **ABSTRACT**

The invention relates to a plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of said plate. The plate comprises an angled member or rib which is inclined according to an angle of between about 30° and 60° in relation to the plane defined by the plate. The angled member or rib has a hole for engaging a screw and is located in the central part of the width, over a determined part of the length of the plate, so that the screw brings the two bone parts into a compressive position.

40 Claims, 2 Drawing Sheets



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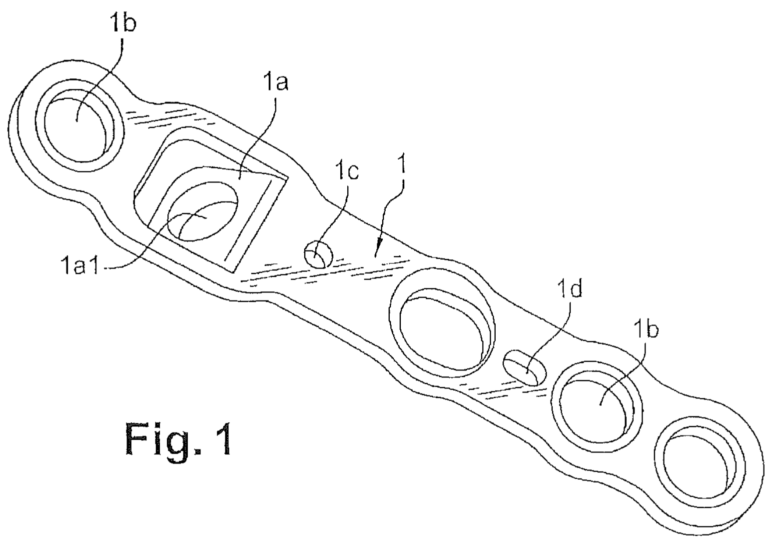

Fig. 1

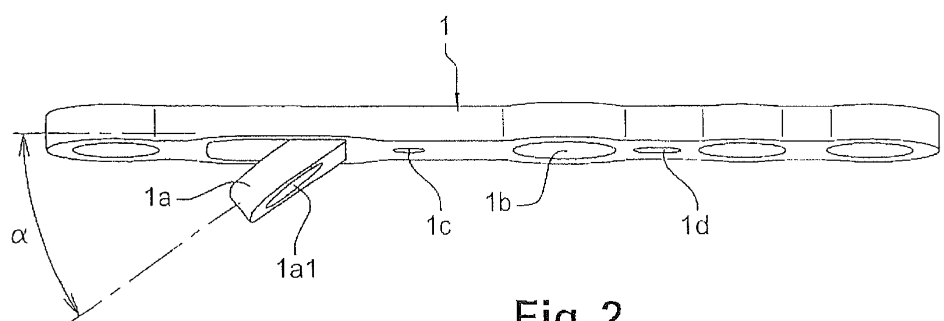

Fig. 2

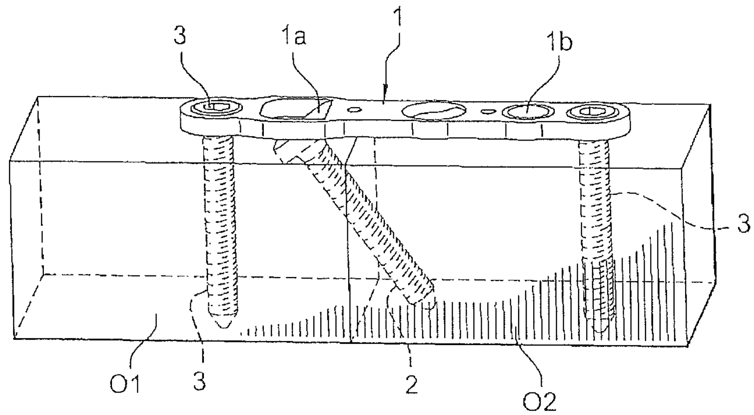

Fig. 3

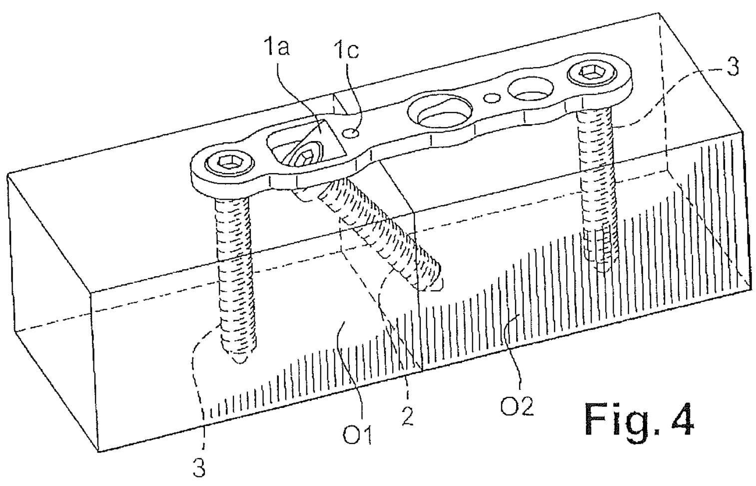

Fig. 4

ORTHOPEDIC IMPLANT IN THE FORM OF A PLATE TO BE FIXED BETWEEN TWO BONE PARTS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/918,071, filed on Oct. 29, 2010, which is a national phase entry under 35 U.S.C. §371 of International Application No. PCT/FR2009/051879, filed Oct. 2, 2009, published in French, which claims priority from French Patent Application No. 0856694, filed Oct. 2, 2008, all of which are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

The invention relates to the technical field of orthopedic implants.

More particularly, the invention relates to a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts.

In a manner known to one having ordinary skill in the art, this type of plate generally has holes for engaging screws, allowing arthrodesis between two bones or osteosynthesis between two bone fragments. This is, for example, the case for bones of the hand or foot, without however excluding other applications, particularly in the field of the spine. Depending on the pathology to be treated, these plates can have a general rectilinear or other geometric shapes.

From this state of the art, one of the objects the invention proposes to attain is to improve, in a sure and efficient manner, compression in a precise direction between the bone parts subjected to the plate.

To attain the given object to enhance the compression between the two relative bone parts, according to the invention, the plate has a formation that orients at least one screw at an angle with respect to a plane defined by the plate, the angle being between about 30° and 60°.

According to an advantageous embodiment, the formation is a tab that is angled according to an angle between 30° and 60°, and having a hole for engaging the screw. The angled tab results from a cut out and a deformation of a portion of the plate.

In another embodiment, the formation is a hole angled at an angle between 30° and 60° for engaging the screw.

Considering the problem to be solved, the formation is located on a determined portion of the length of the plate so that the screw ensures the compression of the two bone parts.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described hereinafter in more detail, with reference to the attached drawings in which:

FIG. **1** is a perspective view of an embodiment of the plate;

FIG. **2** is a side view of the plate;

FIGS. **3** and **4** are perspective views showing the mounting of the plate between two bone parts and their orientation by means of the plate according to the invention, the bone parts being shown schematically.

DETAILED DESCRIPTION

According to the invention, the plate **1** has at least one formation **1***a* adapted to enable the positioning of at least one screw **2**, at an angle α of between 30° and 60° with respect to a plane of the plate (FIG. **2**).

In one embodiment, the formation **1***a* is an angled tab cut out and deformed from the plate. For example, the deformation is made with a cutting-punching operation. This angled tab has a hole **1***a***1** for screw **2**. The angled tab **1***a* is positioned along the length of the plate so that after the screw **2** is fitted to it, the screw ensures the compression together of the two bone parts, as indicated below in the description.

In another embodiment, to allow for an angular orientation of the screw **2** according to an angle between about 30° and 60°, the formation **1***a* can be formed as an angled hole. It must be noted that the tab **1***a* enables adaptation of the angle as a function of the pathology to be treated, given that it is possible to deform this tab at will. In other words, the angle can be adjusted over a few degrees directly by the surgeon in the operating room, using an appropriate tool.

With reference to FIGS. **3** and **4** that show the positioning of the plate **1** between two bone parts O**1** and O**2**:

Once the osteotomies have been carried out, a template of the plate, which does not have a guide formation, enables the position of the tab to be determined.

After determining the position of the tab, the surgeon makes a corresponding recess with the appropriate rasp.

Once the plate having the tab has been positioned, the surgeon sets one or two screws **3**, on a side of the site of the osteosynthesis or the arthrodesis toward the tab. A temporary fastening pin can, possibly, be positioned in a complementary lug.

The screw **2** is then engaged in the hole **1***a***1** of the tab **1***a* to place the fracture in compression.

Once the compression has been done, the surgeon can screw one or several other additional fastening screws **3** and remove the temporary pin.

In a known manner, this plate **1** has smooth and/or threaded holes for the fastening screws **3** set in the bone parts O**1** and O**2** to engage in, as shown in FIGS. **3** and **4**.

Similarly, the plate **1** can have at least one hole **1***c* for a pin for temporarily positioning the plate **1**. Advantageously, the plate **1** can have a guide **1***c* for the insertion of a pin on the side of one of the bone parts O**1** and another guide **1***d* for the insertion of another pin on the side of the other bone part O**2**.

Considering the effect of the desired compression, such as indicated above, the guide **1***c* is a circular hole whose diameter corresponds substantially to that of the pin, whereas the other guide **1***d* can be an elongated slot.

These provisions thus enable the bone to slide under the plate **1** as the screws are set, while ensuring compression along a precise direction, generally axially or parallel to the plate. The pins are of any known and appropriate type, and perfectly known to one having ordinary skill in the art.

The plate **1** can have several shapes, so that the holes **1***a* in particular can be aligned or arrayed, all or in part, according to the corners of a triangle or of a quadrilateral. These provisions, in triangle or in quadrilateral, of the screws, improve the stability of the mounting.

It must be noted also that the plate **1**, no matter its shape, can be longitudinally bent so as to adapt to the curvature of the bone, consequently enabling the screws to form an angle between them.

The advantages are readily apparent from the description.

The invention claimed is:

1. A method of fusing a joint, the method comprising:

spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

inserting a third fixation member through a fixation pathway of the plate, into the first bone, across the joint, and into the second bone, wherein the fixation pathway extends from a top surface of the plate and towards the second bone, and wherein the fixation pathway is arranged at least partially through an extension, at least a portion of which is positioned below a bottom surface of the plate and between first and second sides of the plate, wherein the fixation pathway terminates at an exit hole, and insertion of the third fixation member through the fixation pathway results in the third fixation member extending through the exit hole, across the joint, and into the second bone.

2. The method of claim **1**, wherein insertion of the third fixation member through the fixation pathway includes inserting the third fixation member from the top surface of the plate directly into the exit hole.

3. The method of claim **1**, wherein the fixation pathway is spaced apart from the extension so as to form a gap between the pathway and the extension.

4. The method of claim **1**, wherein the extension is angled by about between 30° and 60° with respect to a longitudinal axis of the plate.

5. The method of claim **1**, further comprising forming a cavity in the first bone with a tool, and positioning the extension at least partially within the cavity.

6. The method of claim **1**, wherein the extension extends from the bottom surface of the bone plate.

7. The method of claim **1**, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into the first bone while some of the fixation members extend into the second bone.

8. The method of claim **7**, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

9. The method of claim **1**, wherein the first and second holes are locking holes.

10. The method of claim **9**, wherein the first and second holes include threading for engaging with the first and second fixation members.

11. The method of claim **1**, wherein the fixation pathway includes non-threaded interior walls.

12. The method of claim **1**, further comprising the step of inserting a first temporary fixation pin into a first pin hole in the plate to temporarily affix the plate to bone.

13. The method of claim **12**, further comprising the step of inserting a second temporary fixation pin into a second pin hole in the plate to temporarily affix the plate to bone.

14. The method of claim **13**, further comprising the step of axially translating the second fixation pin within the second pin hole during compression of the first and second bones.

15. The method of claim **14**, wherein the second pin hole is an elongate slot.

16. The method of claim **1**, wherein the extension is a tab angled relative to a longitudinal axis of the plate.

17. A method of fusing together first and second bone parts, the method comprising:

forming a cavity in at least one of the first and second bone parts;

associating a bone plate with the first and second bone parts, such that the bone plate spans across the first and second bone parts and at least a first hole of the bone plate is aligned with the first bone part;

inserting a first fixation member through the first hole and into the first bone part;

positioning an extension of the plate at least partially within the cavity, the extension being recessed at least partially below a bottom surface of the plate; and

inserting a second fixation member through a fixation pathway of the plate, into the first bone part, across a divide between the bone parts, and into the second bone part, the fixation pathway extending from a top surface of the plate downwards towards the extension, the fixation pathway being arranged at least partially through the extension, wherein the fixation pathway terminates at an exit hole, and insertion of the second fixation member through the fixation pathway results in the second fixation member extending through the exit hole, across the divide between the bone parts, and into the second bone.

18. The method of claim **17**, wherein the bone plate includes holes for fixation members on either side of the extension.

19. The method of claim **17**, wherein insertion of the second fixation member through the fixation pathway includes inserting the second fixation member from the top surface of the plate directly into the exit hole.

20. The method of claim **17**, wherein the exit hole is formed through the extension.

21. The method of claim **20**, wherein the fixation pathway includes non-threaded interior walls.

22. The method of claim **20**, further comprising inserting a third fixation member through a third hole in the plate and into at least one of the first and second bone parts.

23. The method of claim **17**, wherein the first and second bone parts are separated by a joint, and the method further comprises inserting a third fixation member through a third hole in the plate and into the second bone part.

24. The method of claim **23**, wherein insertion of the second fixation member through the fixation pathway includes inserting the second fixation member across the joint.

25. The method of claim **17**, wherein the first hole is a locking hole.

26. The method of claim **17**, wherein a central axis of the second hole diverges from a central axis of the first hole.

27. The method of claim **26**, further comprising associating a template of the bone plate with at least one of the first and second bone parts to determine the positioning of the extension.

28. The method of claim **27**, wherein the template does not include an extension.

29. The method of claim **17**, wherein the plate includes a set of pin holes adapted to receive temporary fixation pins, a first of the pin holes having an axis extending into the first bone part, and a second of the pin holes having an axis extending into the second bone part.

30. The method of claim **29**, further comprising inserting first and second temporary fixation pins into each of the first and second pin holes, and axially translating the second fixation pin within the second pin hole during compression of the first and second bone parts.

31. The method of claim **20**, wherein the extension is angled by about between 30° and 60° with respect to a longitudinal axis of the plate.

32. A method of fusing a joint, the method comprising:

spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and a head of the third fixation member is seated in the third hole, the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate, wherein the third fixation member is the only fixation member extending across the joint.

33. The method of claim **32**, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

34. The method of claim **32**, wherein the first and second holes are locking holes.

35. The method of claim **34**, wherein the first and second holes are threaded.

36. The method of claim **32**, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

37. The method of claim **36**, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

38. The method of claim **37**, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

39. The method of claim **32**, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

40. The method of claim **1**, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

* * * * *

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(12) **United States Patent**
Prandi et al.

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(45) **Date of Patent: *May 4, 2021**

(54) **ORTHOPEDIC IMPLANT IN THE FORM OF A PLATE TO BE FIXED BETWEEN TWO BONE PARTS**

(71) Applicant: **Stryker European Operations Holdings LLC**, Kalamazoo, MI (US)

(72) Inventors: **Bernard Prandi**, Rennes (FR); **Keith Wapner**, Philadelphia, PA (US); **Charles P. Wapner**, Media, PA (US); **Peter W. Wapner**, Media, PA (US)

(73) Assignee: **Stryker European Operations Holdings LLC**, Kalamazoo, MI (US)

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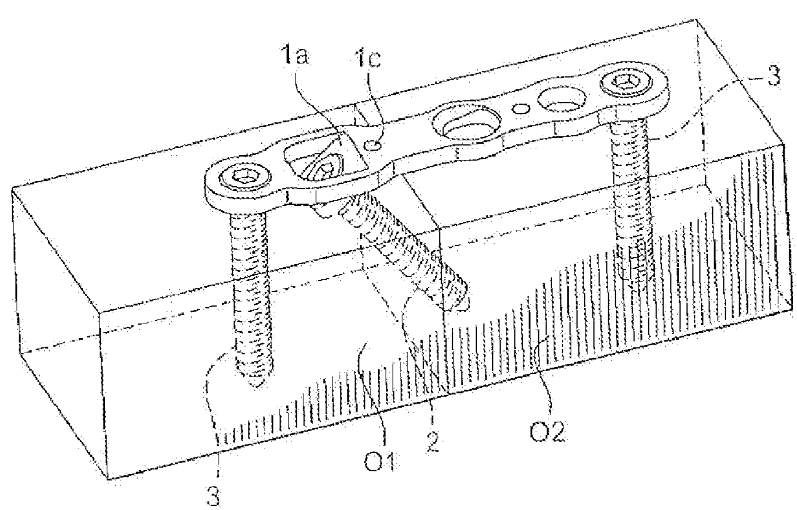
Primary Examiner — Christopher J Beccia
(74) *Attorney, Agent, or Firm* — Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) **ABSTRACT**

The invention relates to a plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of said plate. The plate comprises an angled member or rib which is inclined according to an angle of between about 30° and 60° in relation to the plane defined by the plate. The angled member or rib has a hole for engaging a screw and is located in the central part of the width, over a determined part of the length of the plate, so that the screw brings the two bone parts into a compressive position.

18 Claims, 2 Drawing Sheets



Related U.S. Application Data

No. 15/130,147, filed on Apr. 15, 2016, now Pat. No. 10,349,988, which is a continuation of application No. 14/734,676, filed on Jun. 9, 2015, now Pat. No. 9,333,013, which is a continuation of application No. 14/041,706, filed on Sep. 30, 2013, now Pat. No. 9,078,713, which is a continuation of application No. 12/918,071, filed as application No. PCT/FR2009/051879 on Oct. 2, 2009, now Pat. No. 8,556,946.

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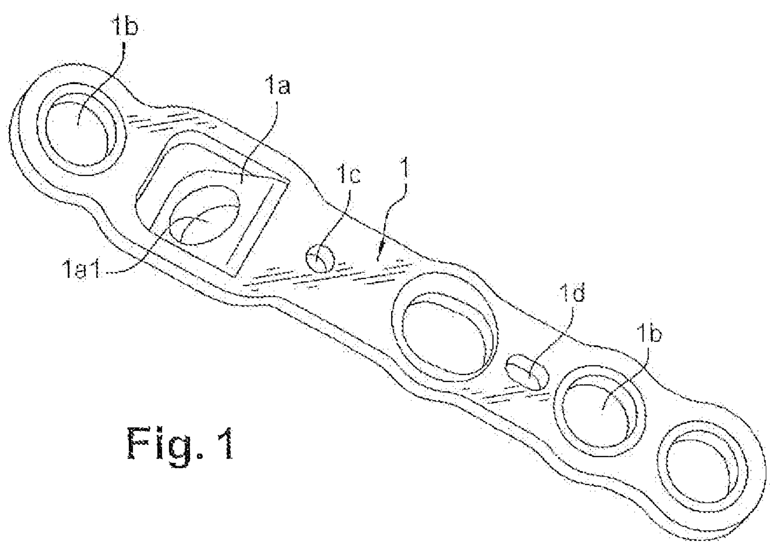

Fig. 1

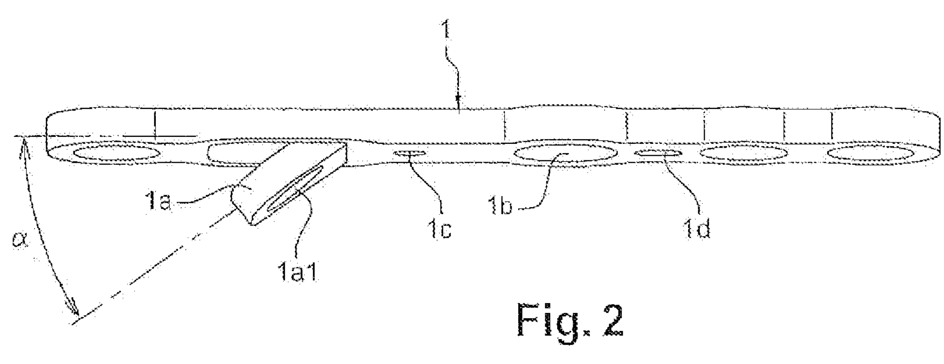

Fig. 2

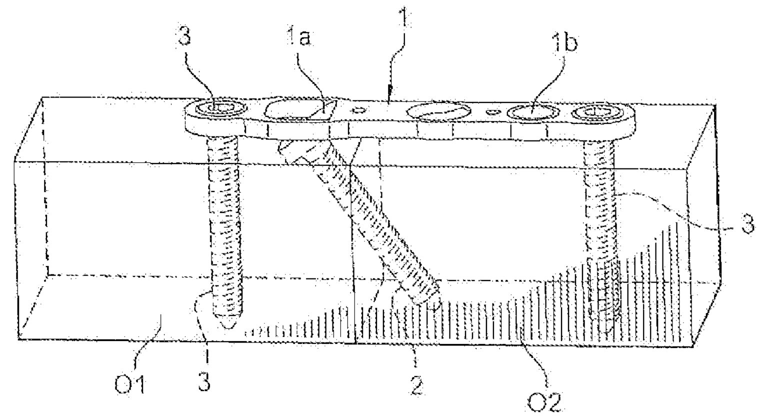

Fig. 3

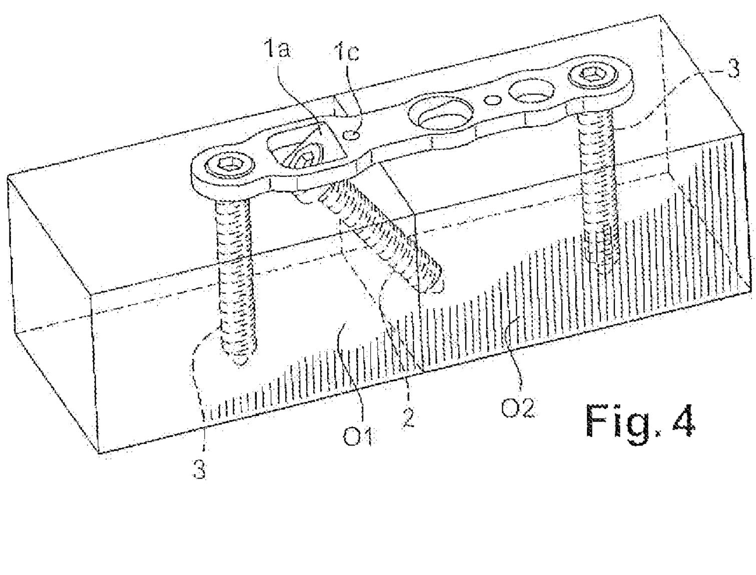

Fig. 4

ORTHOPEDIC IMPLANT IN THE FORM OF A PLATE TO BE FIXED BETWEEN TWO BONE PARTS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 16/429,834, filed Jun. 3, 2019, which is a continuation of U.S. application Ser. No. 15/130,147, filed Apr. 15, 2016 and now U.S. Pat. No. 10,349,988, which is a continuation of U.S. application Ser. No. 14/734,676, filed Jun. 9, 2015 and now U.S. Pat. No. 9,333,013, which is a continuation of U.S. application Ser. No. 14/041,706, filed Sep. 30, 2013 and now U.S. Pat. No. 9,078,713, which is a continuation of U.S. application Ser. No. 12/918,071, filed Oct. 29, 2010 and now U.S. Pat. No. 8,556,946, which is a national phase entry under 35 U.S.C. § 371 of International Application No. PCT/FR2009/051879, filed Oct. 2, 2009, published in French, which claims priority from French Patent Application No. 0856694, filed Oct. 2, 2008, all of which are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

The invention relates to the technical field of orthopedic implants.

More particularly, the invention relates to a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts.

In a manner known to one having ordinary skill in the art, this type of plate generally has holes for engaging screws, allowing arthrodesis between two bones or osteosynthesis between two bone fragments. This is, for example, the case for bones of the hand or foot, without however excluding other applications, particularly in the field of the spine. Depending on the pathology to be treated, these plates can have a general rectilinear or other geometric shapes.

From this state of the art, one of the objects the invention proposes to attain is to improve, in a sure and efficient manner, compression in a precise direction between the bone parts subjected to the plate.

To attain the given object to enhance the compression between the two relative bone parts, according to the invention, the plate has a formation that orients at least one screw at an angle with respect to a plane defined by the plate, the angle being between about 30° and 60°.

According to an advantageous embodiment, the formation is a tab that is angled according to an angle between 30° and 60°, and having a hole for engaging the screw. The angled tab results from a cut out and a deformation of a portion of the plate.

In another embodiment, the formation is a hole angled at an angle between 30° and 60° for engaging the screw.

Considering the problem to be solved, the formation is located on a determined portion of the length of the plate so that the screw ensures the compression of the two bone parts.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described hereinafter in more detail, with reference to the attached drawings in which:

FIG. **1** is a perspective view of an embodiment of the plate;

FIG. **2** is a side view of the plate;

FIGS. **3** and **4** are perspective views showing the mounting of the plate between two bone parts and their orientation by means of the plate according to the invention, the bone parts being shown schematically.

DETAILED DESCRIPTION

According to the invention, the plate **1** has at least one formation **1***a* adapted to enable the positioning of at least one screw **2**, at an angle a of between 30° and 60° with respect to a plane of the plate (FIG. **2**).

In one embodiment, the formation **1***a* is an angled tab cut out and deformed from the plate. For example, the deformation is made with a cutting-punching operation. This angled tab has a hole **1***a***1** for screw **2**. The angled tab **1***a* is positioned along the length of the plate so that after the screw **2** is fitted to it, the screw ensures the compression together of the two bone parts, as indicated below in the description.

In another embodiment, to allow for an angular orientation of the screw **2** according to an angle between about 30° and 60°, the formation **1***a* can be formed as an angled hole. It must be noted that the tab **1***a* enables adaptation of the angle as a function of the pathology to be treated, given that it is possible to deform this tab at will. In other words, the angle can be adjusted over a few degrees directly by the surgeon in the operating room, using an appropriate tool.

With reference to FIGS. **3** and **4** that show the positioning of the plate **1** between two bone parts O**1** and O**2**:

Once the osteotomies have been carried out, a template of the plate, which does not have a guide formation, enables the position of the tab to be determined.

After determining the position of the tab, the surgeon makes a corresponding recess with the appropriate rasp.

Once the plate having the tab has been positioned, the surgeon sets one or two screws **3**, on a side of the site of the osteosynthesis or the arthrodesis toward the tab. A temporary fastening pin can, possibly, be positioned in a complementary lug.

The screw **2** is then engaged in the hole **1***a***1** of the tab **1***a* to place the fracture in compression.

Once the compression has been done, the surgeon can screw one or several other additional fastening screws **3** and remove the temporary pin.

In a known manner, this plate **1** has smooth and/or threaded holes for the fastening screws **3** set in the bone parts O**1** and O**2** to engage in, as shown in FIGS. **3** and **4**.

Similarly, the plate **1** can have at least one hole **1***c* for a pin for temporarily positioning the plate **1**. Advantageously, the plate **1** can have a guide **1***c* for the insertion of a pin on the side of one of the bone parts O**1** and another guide **1***d* for the insertion of another pin on the side of the other bone part O**2**.

Considering the effect of the desired compression, such as indicated above, the guide **1***c* is a circular hole whose diameter corresponds substantially to that of the pin, whereas the other guide **1***d* can be an elongated slot.

These provisions thus enable the bone to slide under the plate **1** as the screws are set, while ensuring compression along a precise direction, generally axially or parallel to the plate. The pins are of any known and appropriate type, and perfectly known to one having ordinary skill in the art.

The plate **1** can have several shapes, so that the holes **1***a* in particular can be aligned or arrayed, all or in part, according to the corners of a triangle or of a quadrilateral. These provisions, in triangle or in quadrilateral, of the screws, improve the stability of the mounting.

It must be noted also that the plate **1**, no matter its shape, can be longitudinally bent so as to adapt to the curvature of the bone, consequently enabling the screws to form an angle between them.

The advantages are readily apparent from the description.

The invention claimed is:

1. A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:

a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:

a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint;

a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and

a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate;

a first fixation member configured to be inserted through the first hole of the bone plate and into the first discrete bone of the joint;

a second fixation member configured to inserted through said second hole of said bone plate and into the second discrete bone of said joint; and

a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in the second discrete bone, wherein said third fixation member is the only fixation member extending across said joint from the first side of the joint to the second side of the joint.

2. The system of claim **1** wherein said bone plate is contoured to anatomically fit bones in a human foot.

3. The system of claim **1** wherein said joint is a metatarsophalangeal joint.

4. The system of claim **1** wherein said joint is a naviculocuneiform joint.

5. The system of claim **1** wherein said joint is a calcaneocuboid joint.

6. The system of claim **1** wherein said joint is a tarsometatarsal joint.

7. The system of claim **1** wherein said third fixation member is configured to develop compression across said joint with lag effect when said third fixation member is tightened.

8. The system of claim **1** wherein the free end of said third fixation member and a free end of said second fixation member are configured to reside adjacent each other within said second discrete bone.

9. The system of claim **1** wherein said bone plate includes at least one pin hole adjacent said first hole, said pin hole configured to receive a temporary fixation member.

10. The system of claim **1** wherein said bone plate includes at least one pin hole adjacent said second hole, said pin hole configured to receive a temporary fixation member.

11. A system for fusing first and second bone parts, said system comprising:

a bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint, said bone plate having;

a first hole configured to align with the first bone part,

a second hole configured to align with the second bone part,

a third hole and a fourth located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area, and

a fifth hole located adjacent either the first hole or the second hole, said fifth hole being smaller in area than said first hole or said second hole;

a first fixation member configured to be inserted through the first hole of said bone plate and into the first bone part;

a second fixation member configured to be inserted through the second hole of said bone plate and into the second bone part;

a third fixation member configured to be inserted through the third and fourth hole in the bone plate, into the first bone part, across the fracture or joint, and into the second bone part, wherein a free end of said third fixation member does not attach to any portion of the bone plate and wherein the third fixation member is the only fixation member extending across the fracture or joint, the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area; and

a temporary fixation member configured to be inserted through the fifth hole in the bone plate.

12. The system of claim **11** wherein the bone plate is contoured to anatomically fit bones in a human foot.

13. The system of claim **11** wherein the free end of the third fixation member and a free end of the second fixation member are configured to reside adjacent each other within said second bone part.

14. The system of claim **11** wherein the bone plate is substantially planar.

15. The system of claim **11** wherein the fifth hole is a pin hole.

16. The system of claim **11** wherein the temporary fixation member is a guide pin.

17. An orthopedic implant comprising;

a bone plate having a proximal surface and an opposite distal bone contacting surface, said bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint,

said bone plate having a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw,

a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw,

a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate,

and a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member.

18. The orthopedic implant of claim **17** wherein the temporary fixation is a guide pin.

* * * * *

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

October 30, 2023
(Date)

THIS IS TO CERTIFY that the attached document is a list of the papers that comprise the record before the Patent Trial and Appeal Board (PTAB) for the *Inter Partes Review* proceeding identified below.

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

Case: IPR2022-00487
Patent No. 9,078,713 B2

By authority of the

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

Prosecution History ~ IPR2022-00487

Date	Document
1/28/2022	Petition for Inter Partes Review
1/28/2022	Petitioner's Petitioner Power of Attorney
2/14/2022	Notice of Filing Date Accorded to Petition and Time for Filing Patent Owner's Preliminary Response
2/18/2022	Patent Owner's Mandatory Notices
2/18/2022	Patent Owner's Power of Attorney
5/16/2022	Patent Owner's Exhibit List
5/16/2022	Patent Owner's Preliminary Response
8/12/2022	Scheduling Order
8/12/2022	Decision - Institution of Inter Partes Review
9/13/2022	Notice of Deposition - Sherman
9/21/2022	Unopposed Motion for Pro Hac Vice Admission - Ratycz
9/28/2022	Order - Pro Hac Vice Admission - Ratycz
10/6/2022	Patent Owner's Updated Mandatory Notices
10/6/2022	Patent Owner's Updated Power of Attorney
10/18/2022	Notice of Stipulation to Modify Due Dates 1-3
11/18/2022	Patent Owner's Response
11/28/2022	Petitioner's Objections to Patent Owner's Evidence Filed with Patent Owner's Response
1/4/2023	Notice of Deposition - Holmes, Jr., M.D., FAAOS
1/4/2023	Notice of Deposition - Leinsing, MSME, PE
1/13/2023	Unopposed Motion for Pro Hac Vice Admission - Beane
1/13/2023	Petitioner's Updated Mandatory Notice
1/13/2023	Petitioner's Power of Attorney
1/23/2023	Order - Pro Hac Vice Admission - Beane
2/9/2023	Notice of Stipulation to Modify Due Dates 2-3
2/17/2023	Petitioner's Reply in Support of Petition for Inter Partes Review
2/24/2023	Patent Owner's Objections to Petitioner's Evidence Submitted with Its Reply
3/17/2023	Patent Owner's Motion to Submit Supplemental Information
3/30/2023	Order - Patent Owner's Motion to Submit Supplemental Information
3/31/2023	Petitioner's Request for Oral Argument
3/31/2023	Patent Owner's Request for Oral Argument
4/7/2023	Patent Owner's Sur-Reply
4/13/2023	Order - Setting Oral Argument
5/9/2023	Patent Owner's Updated Exhibit List
5/9/2023	Petitioner's Updated Exhibit List
5/10/2023	Patent Owner's Objections to Petitioner's Demonstrative Slides
7/13/2023	Oral Hearing Transcript
8/4/2023	Final Written Decision

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

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OSTEOMED LLC,
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STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

Case: IPR2022-00488
Patent No. 10,993,751 B1

By authority of the

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer

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8/8/2023	Final Written Decision

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00487
U.S. PATENT NO. 9,078,713

PETITION FOR *INTER PARTES* REVIEW

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VII. STATEMENT OF PRECISE RELIEF REQUEST AND REASONS THEREFORE

Petitioner requests the institution of IPR and the cancellation of the Challenged Claims on the following Grounds:

Ground	Basis	Reference(s)	Claim(s)
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater (Ex. 1004)	32, 33, 36, 37
2	§103	Slater and U.S. Pat. Pub. No. 2006/0241608 to Myerson et al. ("Myerson") (Ex. 1008)	34, 35, 39
3	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	32, 33, 38
4	§103	E.P. Patent 1897509 to Arnould ("Arnould") (Ex. 1005) and Zahiri	32, 33, 36-39
5	§103	Arnould, Zahiri, and Myerson	34, 35

A. The Petition Should Not Be Discretionarily Denied

1. *Becton, Dickinson*

The claims of the '713 Patent have not been considered in view of any of the prior art relied upon in the asserted grounds of this Petition. Accordingly, the present Petition should not be discretionarily denied under 35 U.S.C. §325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

4. Myerson (Ex. 1008)

Myerson is a U.S. patent application that published on October 26, 2006. (Ex. 1008, Cover). Myerson qualifies as prior art under §102(b).

Myerson discloses a bone plate for joint fusion of the metatarso-phalangeal (MTP) joint in the foot. (Ex. 1008, FIG. 1; ¶2). The bone plate is contoured to follow the anatomy of metatarsal bone and phalanx and engage with the curved surfaces of the bone. (Ex. 1008, ¶10; Ex. 1002, ¶¶71-74).

C. Ground 1: Claims 32, 33, 36 and 37 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Slater

Independent claim 32 and dependent claims 33, 36 and 37 are obvious in view of Slater. (Ex. 1002, ¶¶78-84).

1. Basis for Obviousness in view of Slater

The scope and content of the prior art includes Slater and the technical expertise of a POSITA, which collectively disclose all of the elements of claims 32, 33, 36, and 37. There are no differences between the subject matter of these claims and the combination of Slater and the technical expertise of a POSITA.

Slater discloses a bone plate comprising a fixation screw that is placed at an angle so that it compresses the ankle joint and intersects the tibia, talus, and potentially the calcaneus:

Thus, a POSITA would find this claim obvious in view of Slater and Zahiri. (Ex. 1002, ¶¶186-188).

F. Ground 4: Claims 32, 33 and 36-39 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over the combination of Arnould and Zahiri

Independent claim 32 and dependent claims 33 and 36-39 are obvious in view of the combination of Arnould and Zahiri. (Ex. 1002, ¶189).

1. Basis for the Combination of Arnould and Zahiri

The scope and content of the prior art includes Arnould and Zahiri, which collectively disclose all of the elements of claims 32-33 and 36-39. There are no differences between the subject matter of these claims and the combination of Arnould and Zahiri.

Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone or across a fracture. (Ex. 1006, ¶6; Ex. 1007, 2:20-31). A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture, and therefor Arnould and Zahiri are in analogous fields of art. (Ex. 1002, ¶190-91). Arnould's bone plate comprises a hole 25 that determines the relative position of a screw 30 that passes through and fuses the joint between the metatarsal and phalanx. (Ex. 1006, ¶31). Arnould explains that "the screw works mainly in traction," and that "[w]ith a single action consisting of screwing in this

long screw, the surgeon automatically brings the two bones to be fused closer to each other." (Ex. 1006, ¶6).

A POSITA knows that screws positioned across an interface, "working in traction" are providing compression at the interface. (Ex. 1002, ¶191). Arnould further discloses a variable fixation angle between the longitudinal axis of the plate body, selected by the surgeon to fuse the metatarsal and phalanx. (Ex. 1006, ¶¶27, 32). In other words, the surgeon "has the possibility of modifying the angle α," indicating the surgeon can choose the angle at which the fixation member is inserted to achieve an optimal interface between the screw and the bone. (Ex. 1006, ¶38; Ex. 1002, ¶192).

While a POSITA may find that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate, Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri, and position the third hole at an angle relative to the longitudinal thickness of the bone plate. (Ex. 1002, ¶193). Zahiri discloses a bone plate configured to fuse a first and second bone part with an angle fixation member and compress the bone fracture:

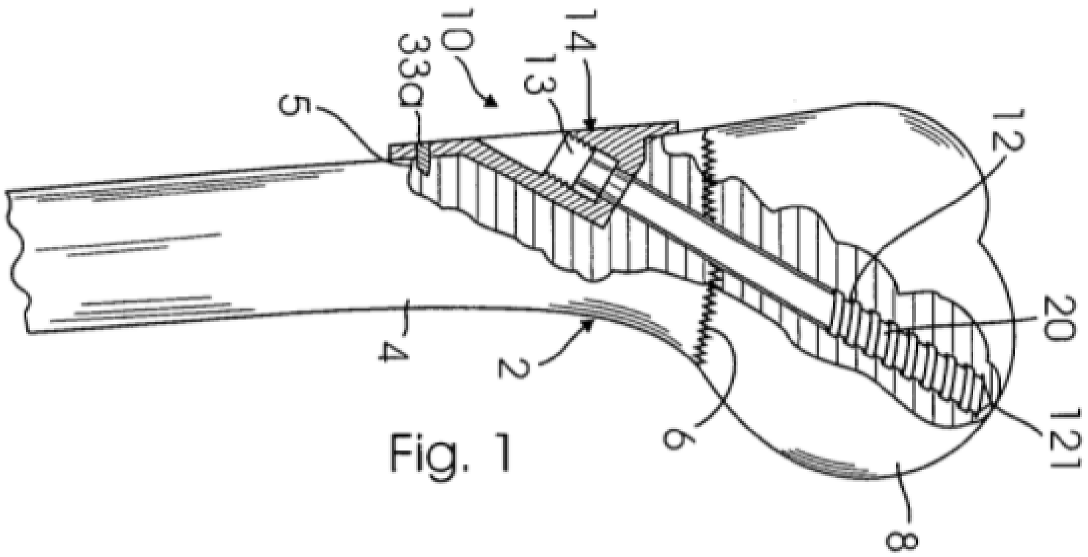
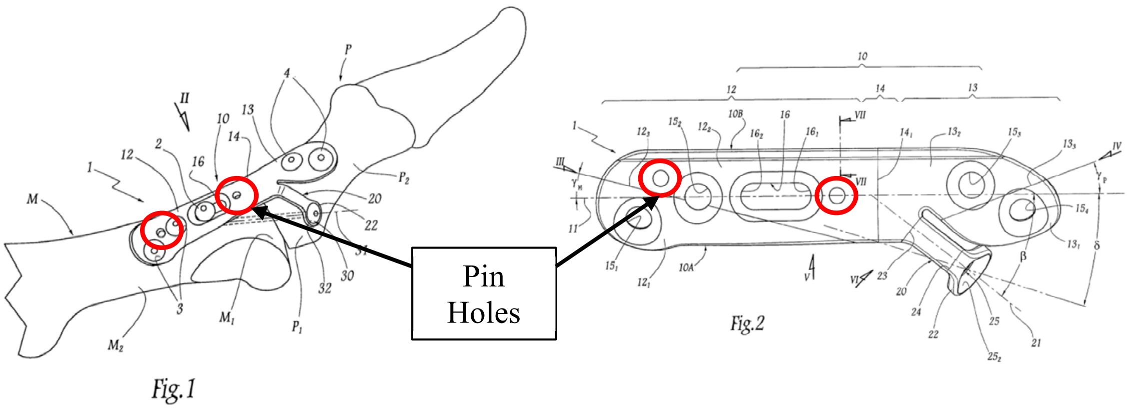


Fig. 1

(Ex. 1007, FIG. 1; 2:45-48). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11). Moreover, there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture, and thus a POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures would be used interchangeably, as they have for decades. (Ex. 1002, ¶193). Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate. (*Id.*).

While Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted, the figures show pin holes that are intended to be used to temporarily secure the plate with k-wires during the implantation process:



(Ex. 1006, FIGS. 1, 2 (annotated); Ex. 1002, ¶194). K-wires are commonly used for temporary placement, alignment and immobilization of bone plates so that the surgeon can correctly position and align a plate. (Ex. 1002, ¶194). Arnould discusses the difficultly of proper plate alignment faced by the surgeon during implantation and the importance that proper placement has on patients' comfort. (Ex. 1006, ¶3). Zahiri further discusses the importance of plate alignment and specifically discloses the use of temporary locking pins to temporarily secure the bone plate to the bone during implantation. (Ex. 1007, 3:10-18). As this would be done before the plate is permanently affixed, a POSITA would look to incorporate the use of temporary pins disclosed by Zahiri into Arnould to ensure correct placement. (*See* Ex. 1006, ¶¶3, 31; *see also* Ex. 1002, ¶194).

Similarly, Zahiri discloses four small holes in the corner of the bone plate that are used with pins to temporarily hold the bone plate in place during implantation:

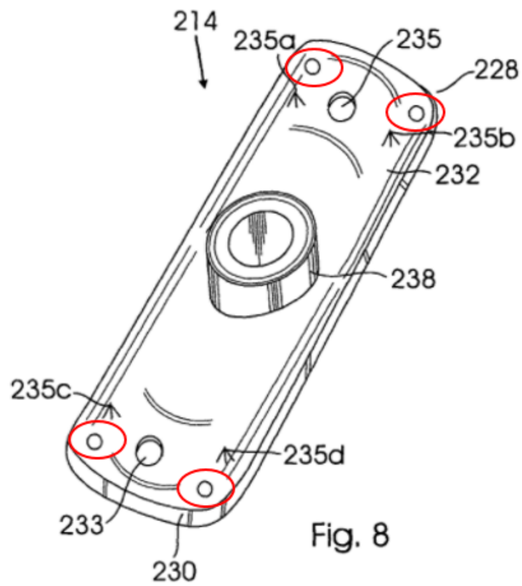


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* 3:10-18 ("[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.")). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (*Id.*). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (*Id.*).

Thus, a POSITA would understand that the temporary pin holes, as disclosed in Zahiri, could be implemented into Arnould's bone plate to temporarily maintain plate alignment during implantation. (Ex. 1002, ¶¶195-96). A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins and would render the incorporation of Zahiri's guide holes

obvious. (Ex. 1006, FIG. 1; Ex. 1002, ¶196). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, ¶196).

Thus, a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement. (Ex. 1002, ¶197).

2. Claims 32, 33 and 36-39 are Obvious in view of the Combination of Arnould and Zahiri

a. *Independent Claim 32*

i. [32Pre] A method of fusing a joint, the method comprising:

Arnould discloses a bone plate configured for arthrodesis of a joint between the first metatarsal and the first phalanx. (Ex. 1006, ¶11 ("Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot.")).

Thus, Arnould discloses a plate that is used to perform the claimed method. (Ex. 1002, ¶¶198-200).

ii. <u>[32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;</u>

Arnould's bone plate comprises four screw holes 15_1-15_4 configured to anchor the plate body to the phalanx (first bone) through holes 15_3-15_4 (first holes), and to the metatarsal (second bone) through holes 15_1-15_2 (second holes):

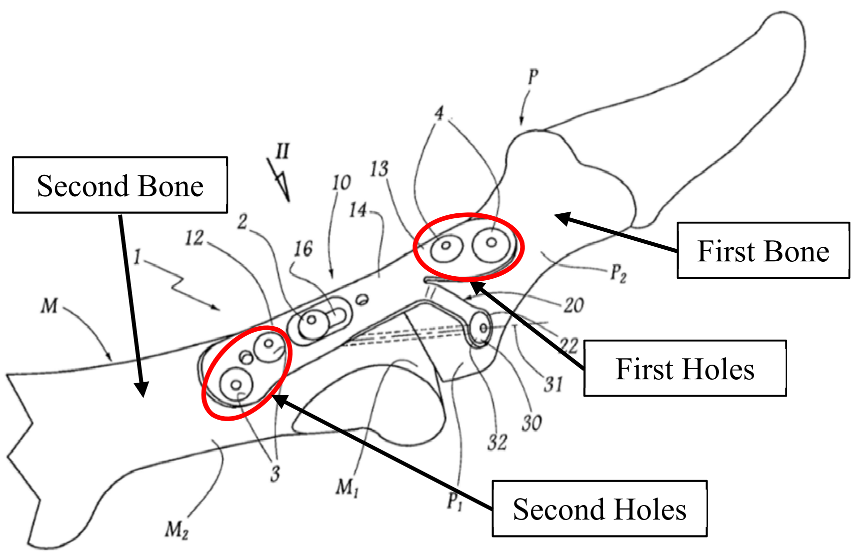


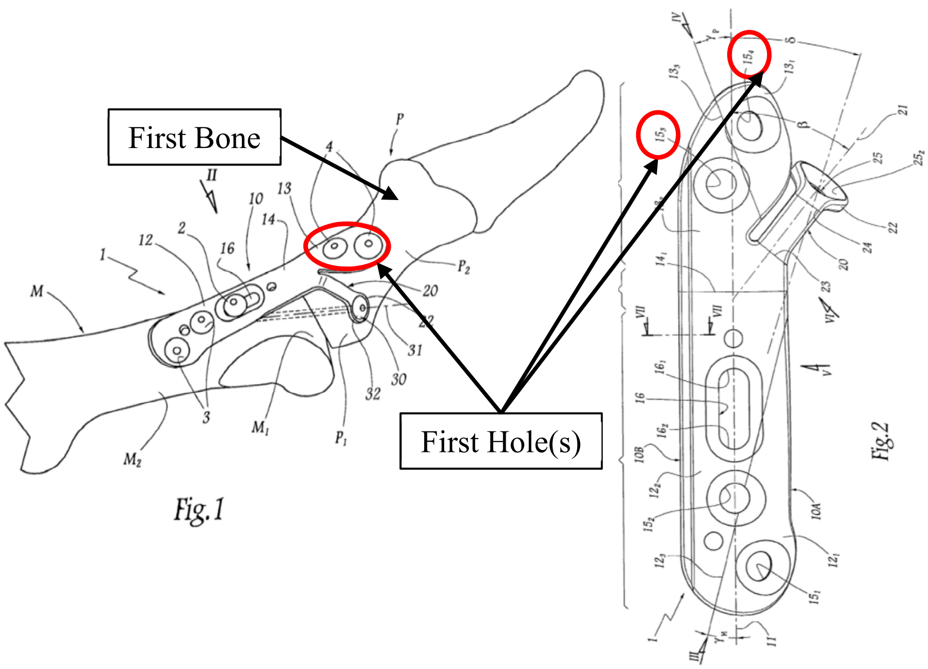
Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* FIG.2; ¶33 ("The screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2."); ¶34 ("Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.")).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶201-03).

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

Arnould discloses the steps of inserting screws 4 into holes 15_3 and 15_4, and attaching to the phalanx (first bone):



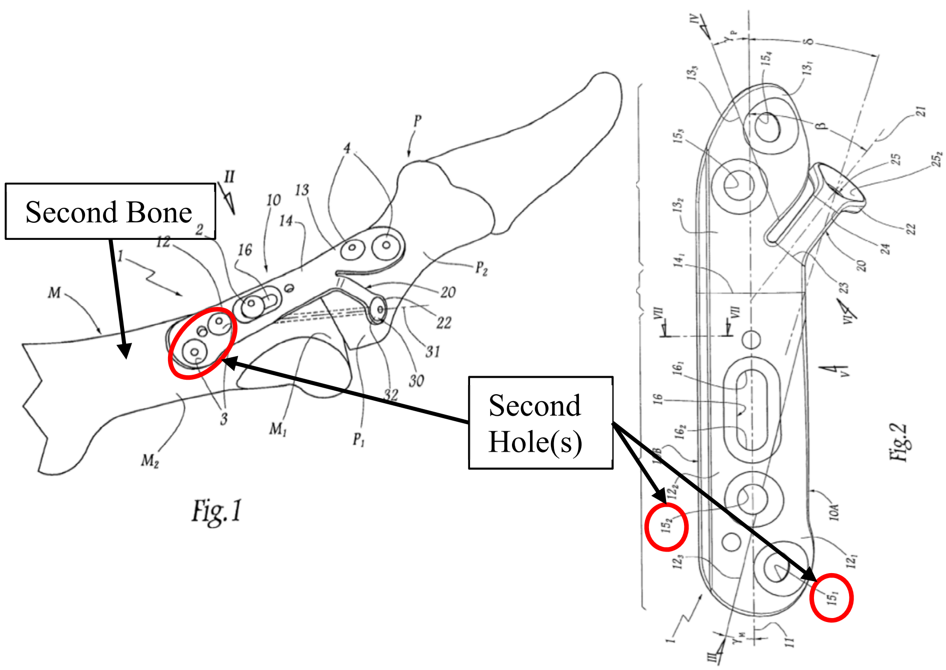
(Ex. 1006, FIGS. 1, 2 (annotated); *see also* ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶34 ("Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into

the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.”)).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶204-07).

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

Arnould discloses the steps of inserting screws 3 into holes 15_1 and 15_2, and attaching to the metatarsal (second bone):



(Ex. 1006, FIGS. 1, 2 (annotated); ¶21 (“In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner.”); ¶33 (“The screw 2 is then

completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2.”)).

Thus, Arnould discloses this element. (Ex. 1002, ¶¶208-11).

v. <u>[32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and</u>

Arnould discloses a screw 30 configured to be inserted into hole 25 that is configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

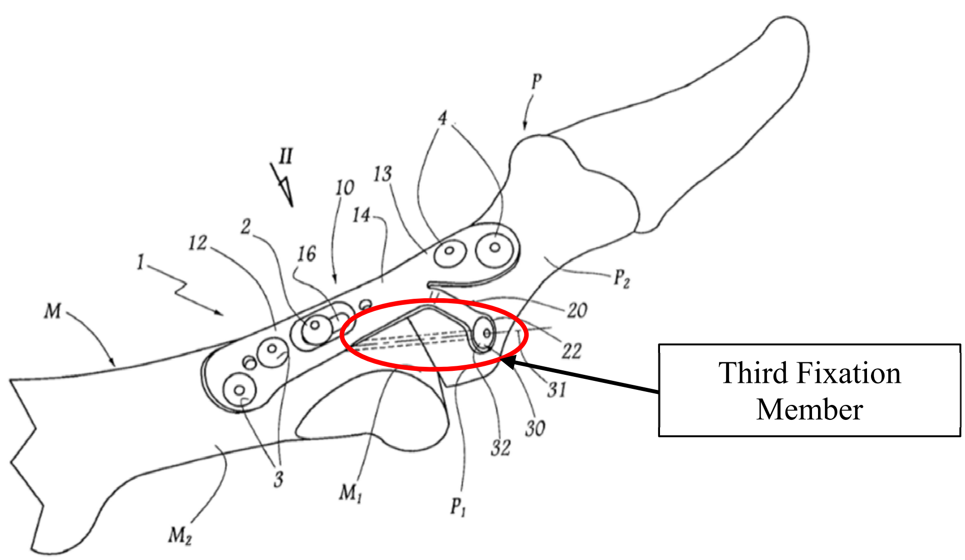


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶32 ("The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above."); Ex. 1002, ¶212). A POSITA would understand that the free end of screw 30 resides in the second bone and does not attach to any portion of the bone plate. (Ex. 1002, ¶213).

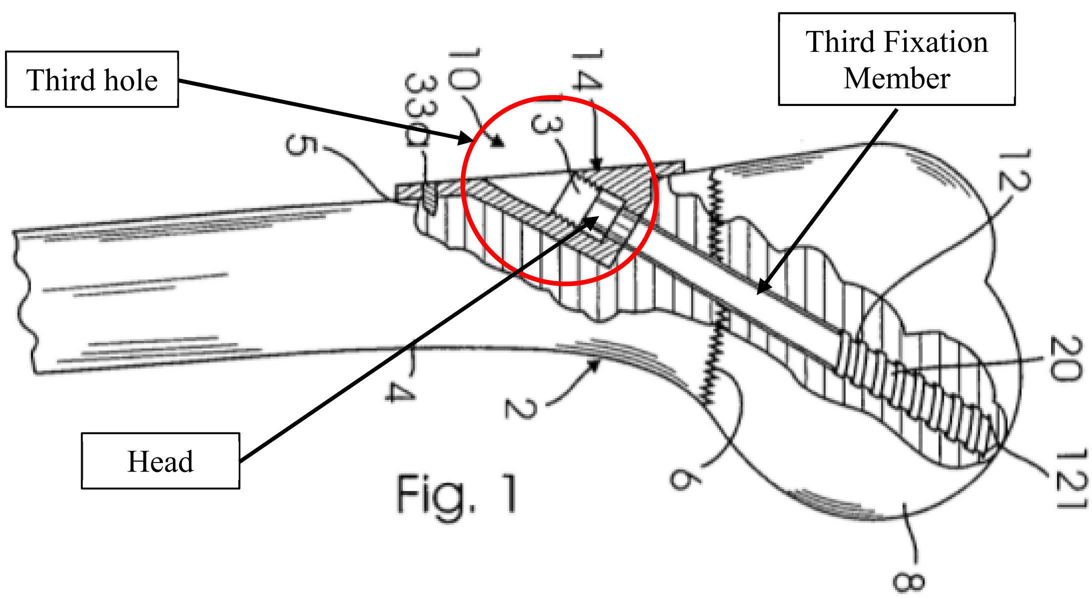
Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶¶212-13).

vi. <u>[32e] a head of the third fixation member is seated in the third hole,</u>

Arnould's bone plate comprises screw 30 configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone). (Ex. 1006, ¶32). Screw 30 is tightened until the head 32 is abutted against the edge of hole 25. (*Id.*). In order for screw 30 to lock in place, hole 25 comprises a concave surface that is substantially complementary with head 32 of screw 30. (Ex. 1006, ¶27). Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶¶214-15).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the placement of

the angled fixation screw. (Ex. 1002, ¶216). Zahiri discloses a threaded portion 37 in the short barrel portion 38 (third hole), which provides a press fit engagement with the head 22 of the lag screw 12 (third fixation member):

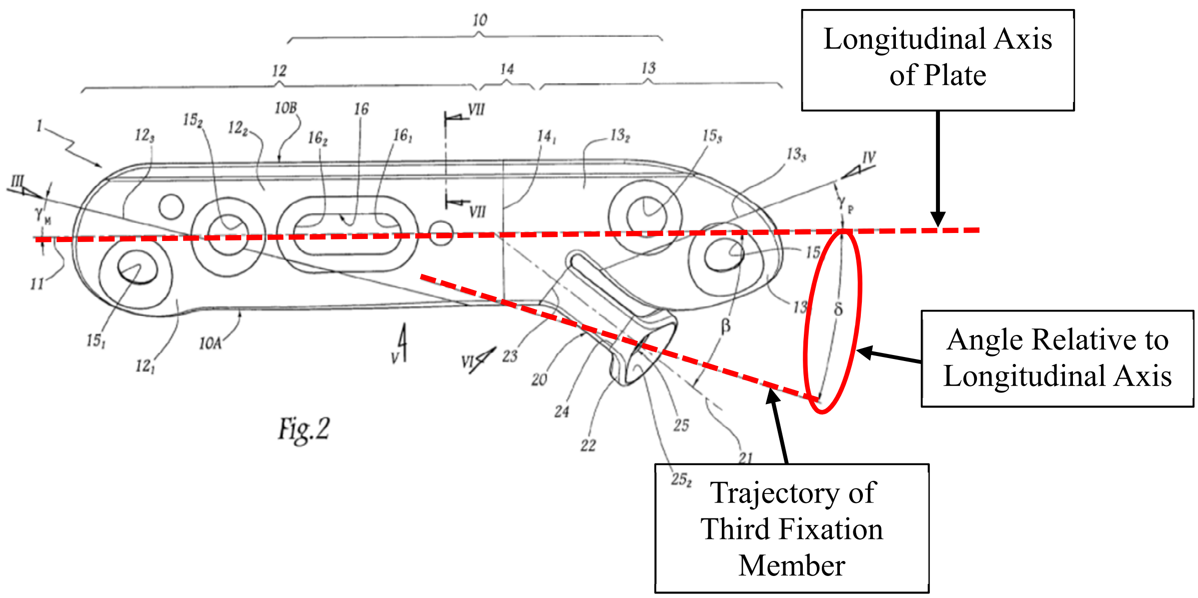


(Ex. 1007, FIG. 1 (annotated); *see also* 7:31-38). Thus, in order to achieve the stated goal from Arnould of locking screw 30 by the head 32, it would be obvious to a POSITA to use the seated head of the lag screw from Zahiri to ensure the third fixation member is seated in the third hole. (Ex. 1002, ¶216).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶217).

vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

Arnould describes a screw hole 25 (third hole) configured such that the screw 30 forms a non-zero angle in relation to the longitudinal axis of the plate body:



(Ex. 1006, FIG. 2 (annotated); *see also* ¶27 ("The hole 25 is provided to receive the screw 30 so that, depending on the direction of observation corresponding to arrow II, the longitudinal axis 31 of this screw can be inclined in relation to the longitudinal direction 11 of the plate body 10, forming a non-zero angle δ with this direction 11."); Ex. 1002, ¶218). Thus, the trajectory of the third fixation member, and therefore the third hole, is angled relative to the longitudinal axis of the plate. (Ex. 1002, ¶218).

Arnould further shows how there is a thickness to the plate where screw 30 is inserted into hole 25:

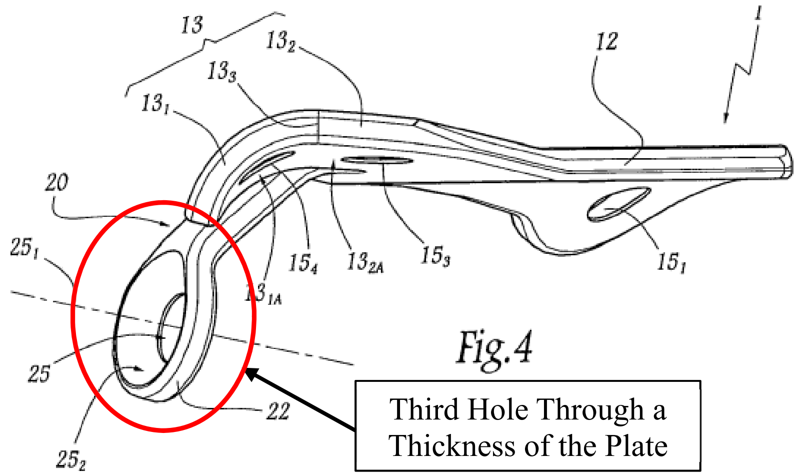
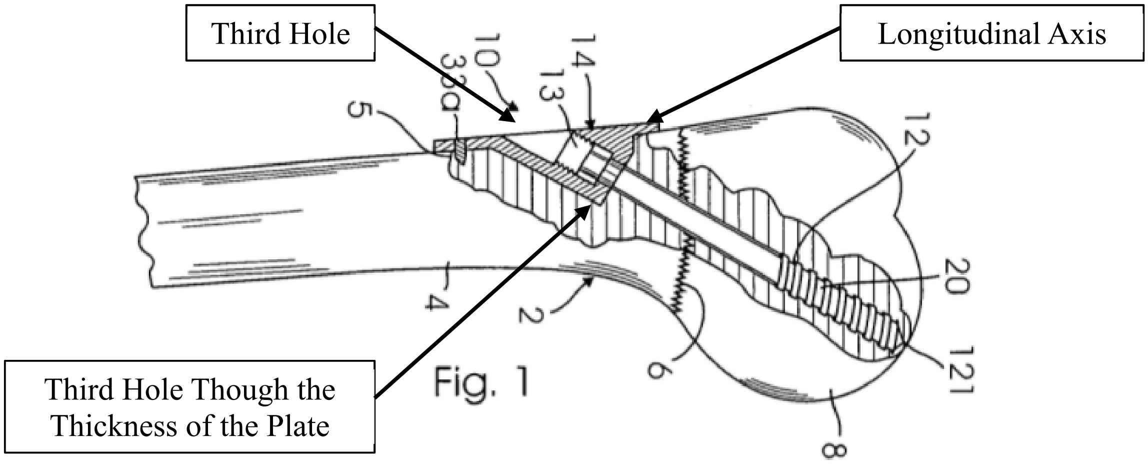


Fig.4

(Ex. 1006, FIG. 4 (annotated); Ex. 1002, ¶219).

Thus, a POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶220).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw, which includes putting the screw through a thickness of the plate:



(Ex. 1007, FIG. 1 (annotated), *see also* 7:63-8:11; Ex. 1002, ¶221).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶222).

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

Arnould depicts a bone plate comprising one hole 25 configured to receive an angled screw 30 that passes through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

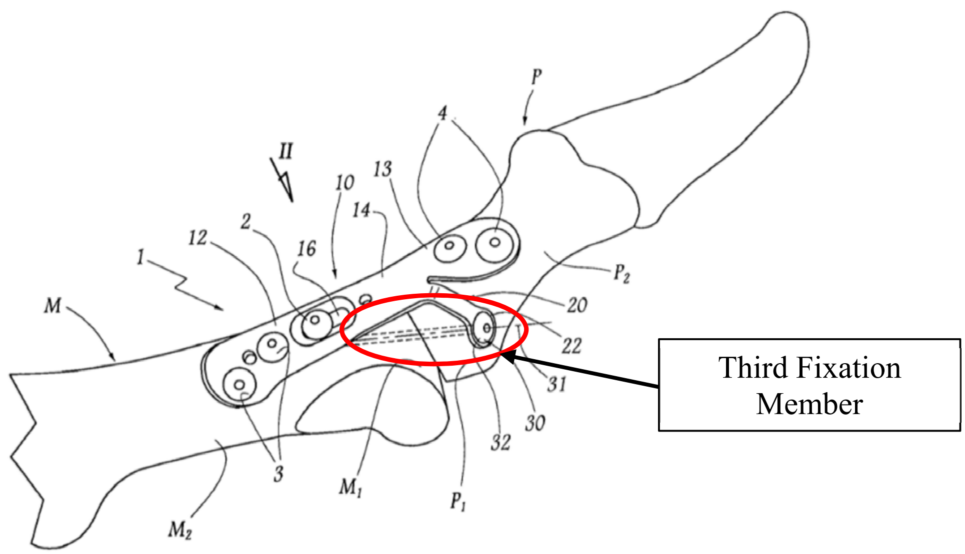


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶32 ("The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above.")).

Additionally, Zahiri depicts a bone plate comprising a guide hole through a barrel portion configured to angle a lag screw through a first bone and into a second bone. (Ex. 1007, 2:23-36). Figure 1 of Zahiri shows that the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone fragment and the second bone fragment:

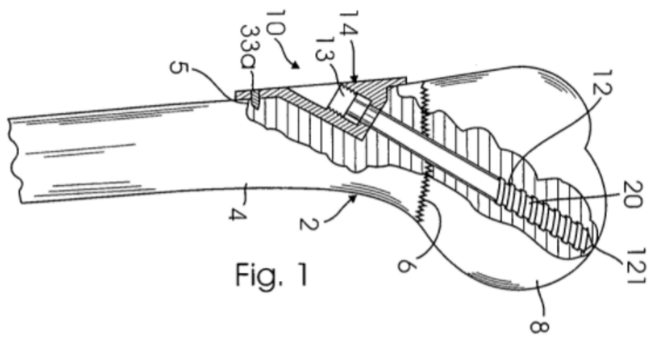


Fig. 1

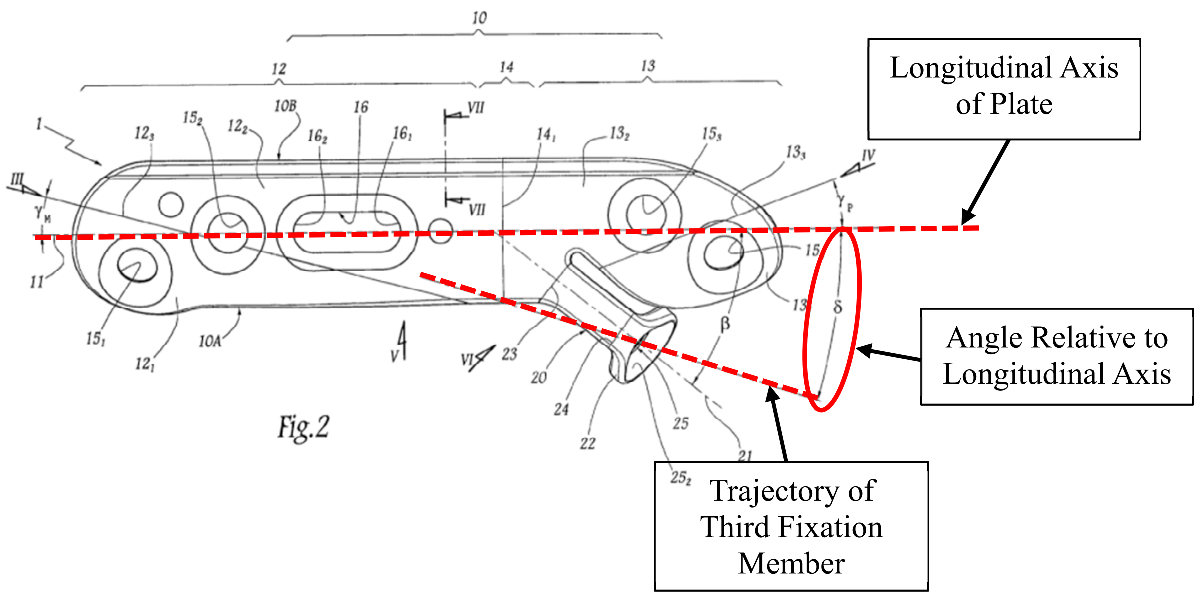
(Ex. 1007, FIG. 1; *see also* 2:23-36). Therefore, a POSITA would understand that both Arnould's bone plate and Zahiri's bone plate are configured for only one compression screw to intersect the joint and/or fracture line. (Ex. 1002, ¶¶223-24).

Thus, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶225).

b. *Dependent Claims 33, 36-39*

i. <u>Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.</u>

Arnould discloses the trajectory of screw 30, and therefore hole 25, forms a non-zero angle relative to the plate body in the longitudinal direction at angle δ, where angle δ is less than 45°:



(Ex. 1006, FIG. 2 (annotated); *see also* ¶27 ("For anatomical reasons, the angle δ is advantageously chosen to be less than 45.")). Hole 25 is further connected to leg 20, where leg 20 is offset at angle β with respect to the longitudinal axis of the plate. (Ex. 1006, ¶25). Thus, a POSITA would understand that the disclosed angle range of Arnould would fall within the claimed angle range. (Ex. 1002, ¶226).

To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶227). Additionally, if the specific application did not allow the leg 20 to wrap around the side of the bone, as shown in Figure 1 of Arnould, a POSITA would look for other plates, such as Zahiri, that are equally applicable to the application. (*Id.*). Give that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone

parts for the purpose of fusing a bone fracture, a POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures would be used interchangeably, as they have for decades. (Ex. 1002, ¶228). Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate. (*Id.*).

Zahiri further discloses an incidence angle of a locking screw "A" that is preferably 90°, 150° or 160° from the guide plate but "in the range of from 90° to 170°." (Ex. 1007, 3:59-67). The incidence angle "A" is measured as the obtuse angle between the guide plate and the locking screw trajectory:

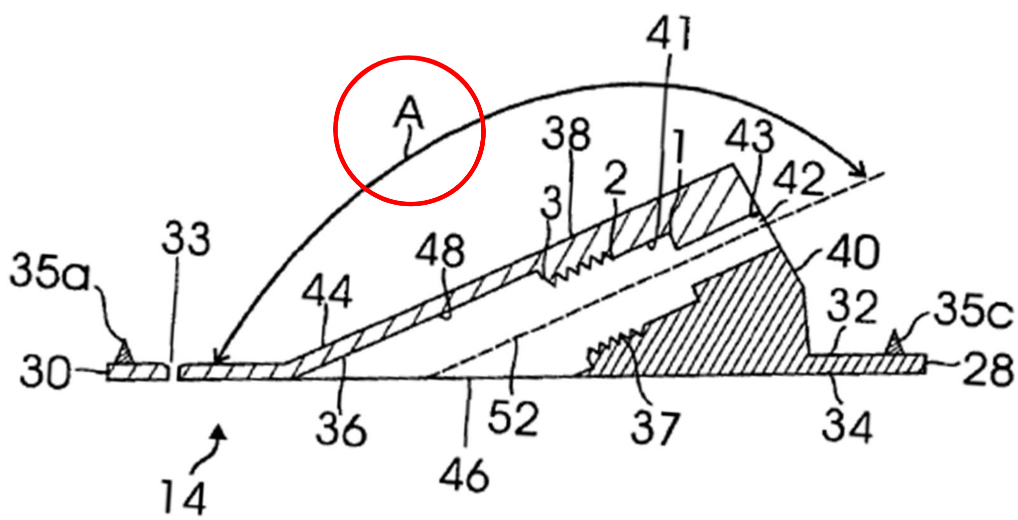
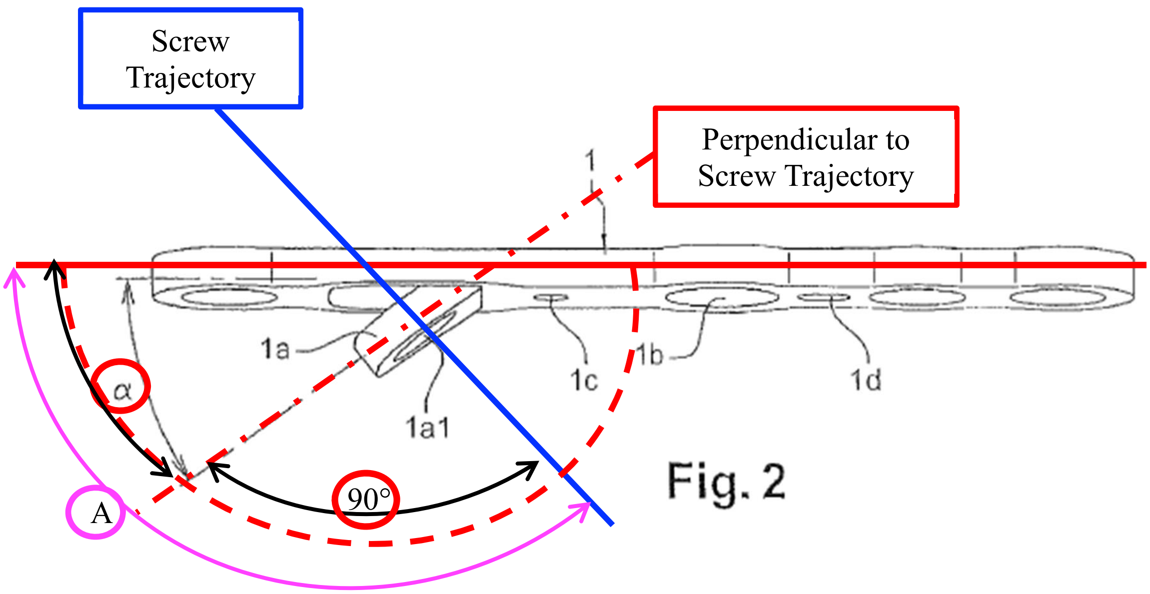


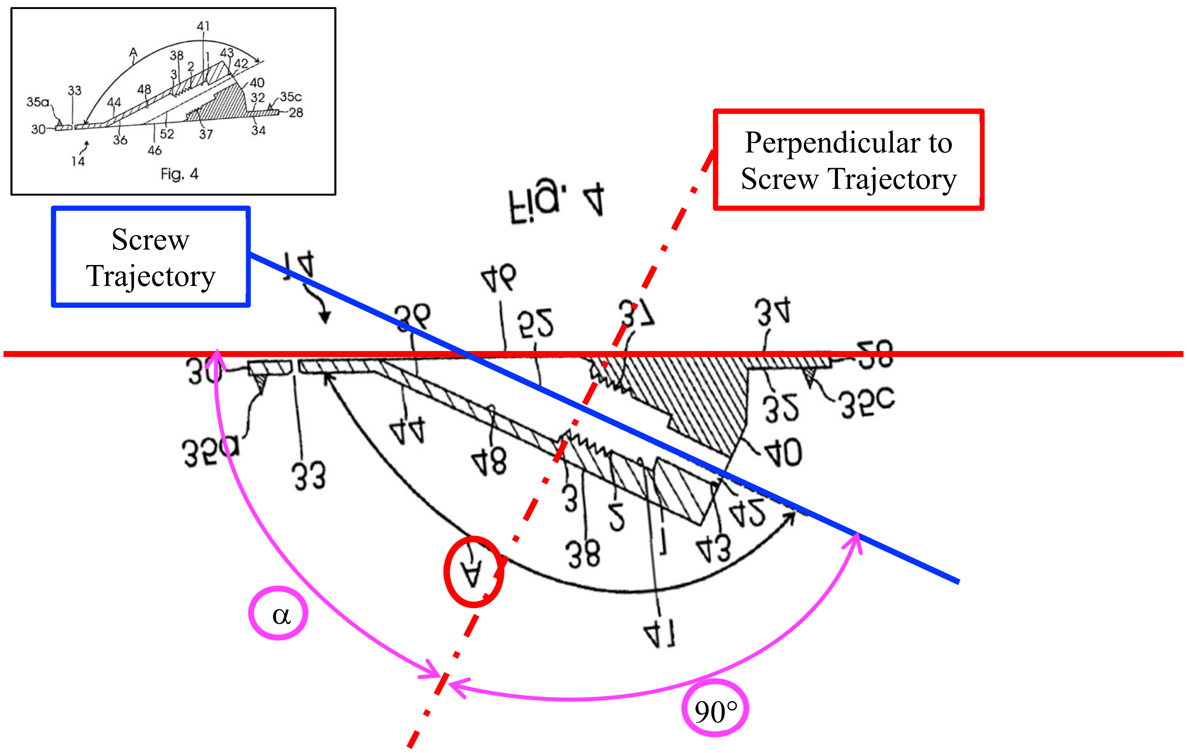
Fig. 4

(Ex. 1007, FIG. 4 (annotated); Ex. 1002, ¶229). In contrast, the '713 Patent refers to angled tab by the angle "α," which is the acute angle between the plate and the tab in Figure 2:



Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°

(Ex. 1001, FIG. 2 (annotated); *see also* Ex. 1002, ¶229). To be comparable to angle "A" in Zahiri, 90° has to be added to "α":



Zahiri's Screw Incidence Angle = "A"
Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°
For example, if Zahiri says that "A" can be 90° - 170°; then '713 Patent α can be 0° - 80°
But Zahiri prefers "A" = 150° or 160°, which equates to α in the '713 Patent equaling 60° - 70°

(Ex. 1007, FIG. 4 (annotated); *see also* Ex. 1002, ¶229). Therefore, the angle of the hole opening "α," is determined by subtracting 90° from A (hole opening "α," = A - 90°). (Ex. 1002, ¶229). Accordingly, Zahiri teaches a hole-opening angle "α," at 0° to 80° with respect to the longitudinal surface of the guide plate. (Ex. 1002, ¶230).

Both Arnould and Zahiri teach a third hole configured at an angle with respect to the longitudinal axis of the plate and that angle encompasses the claimed range. Thus, it would also be obvious to a POSITA that a fixation member configured to

diagonally secure a joint would be angled between 30° and 60° with respect to the longitudinal axis of the plate. (Ex. 1002, ¶230-31).

Thus, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1002, ¶231).

ii. <u>Claim 36: The method of claim 32, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.</u>

Arnould's bone plate comprises four holes 15_1-15_4 configured in a quadrilateral orientation and receive screws 3 and 4:

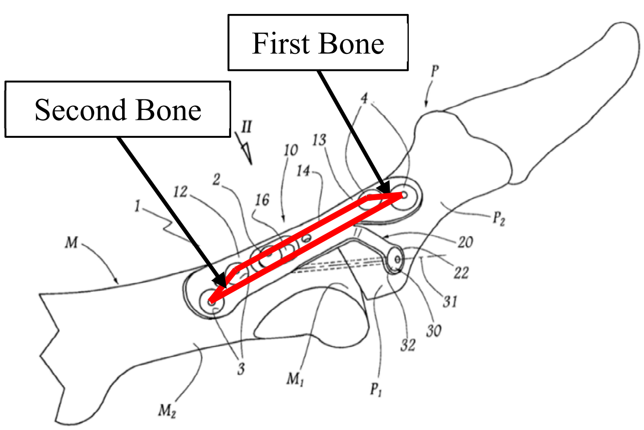


Fig.1

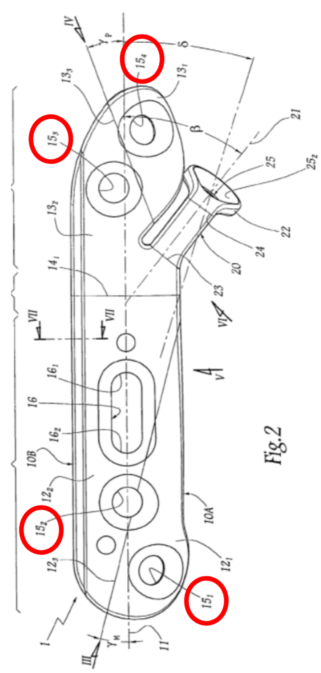


Fig.2

(Ex. 1006, FIGS. 1, 2 (annotated); *see also* ¶21). Holes 15_1 and 15_2 are configured to receive screws 3 and attach to the metatarsal (second bone), and holes 15_3 and 15_4 are configured to receive screws 4 and attach to the phalanx (first bone). (*Id.*).

Additionally, Zahiri's bone plate comprises four holes 31a-d in a rectangular (i.e., quadrilateral) orientation, where the holes are intended for anchoring the plate to the bone:

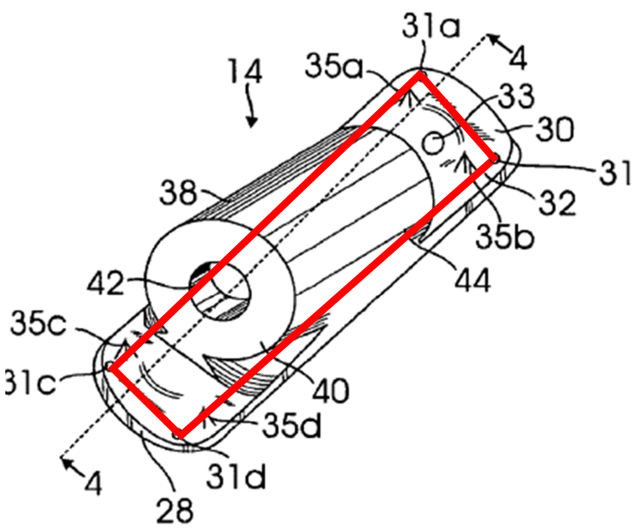


Fig. 3

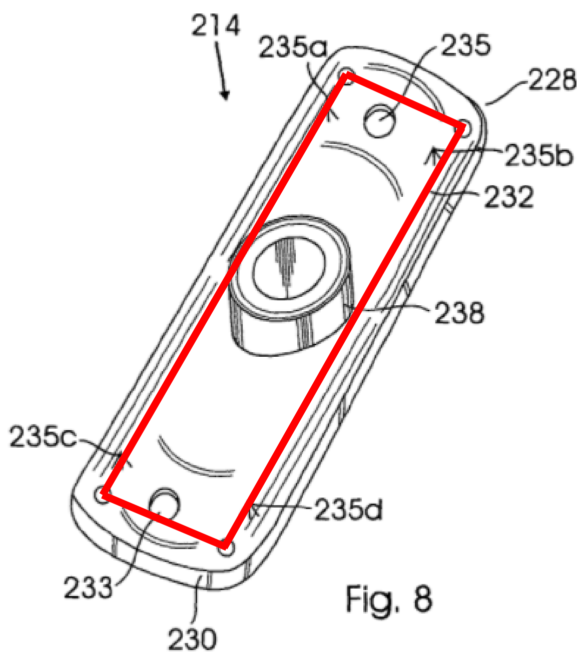


Fig. 8

(Ex. 1007, FIGS. 3, 8 (annotated); *see also* 5:47-49 ("Referring to FIGS. 2 and 3, there is illustrated the guide plate 14 having four small holes 31a, 31b, 31c, and 31d respectively located at each corner of the rectangular plate")). A POSITA looking at Zahiri's plate would recognize that these holes were arranged in a quadrilateral shape and that fixation members would be used in these holes to secure the plate to the

bone. (Ex. 1002, ¶¶232-33). Combining these holes and fixation members from Zahiri with Arnould's plate would result in securing the plate to the first and second bones. (Ex. 1002, ¶233).

Thus, a POSITA would understand that this claim is taught by Arnould and Zahiri. (Ex. 1002, ¶234).

iii. Claim 37[a]: The method of claim 36, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and

Arnould discloses a bone plate comprising predetermined contours necessary to secure to the metatarsal and phalangeal and to conform to the upper surface of the diaphyseal portion of the metatarsal:

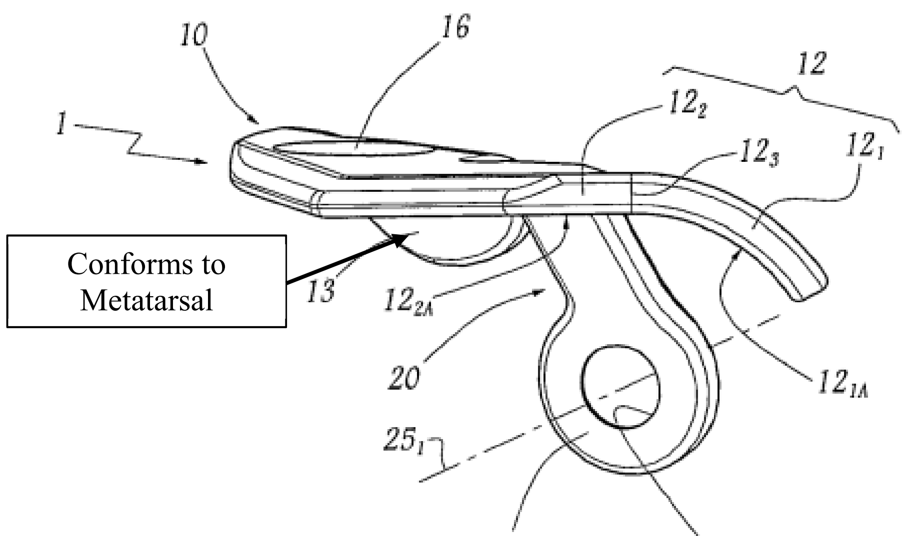


Fig.3

(Ex. 1006, FIG. 3 (annotated); *see also* FIGS. 4, 5, 6; ¶15 ("The concave lower surface 12_{1A} of the bent section 12_1, which is clearly visible in Figure 3, is shaped to

conform to the upper surface of the diaphyseal portion M_2 of the metatarsal M – that is to say, to come into contact with this diaphysis while partially covering it in a fitted manner, as shown in Figure 1."); ¶39 ("This plate is, in a first step, cut in accordance with predetermined contours in order to secure the metatarsal 12 and phalangeal 13 parts, as well as the leg 20.")).

Thus, a POSITA would find this element is taught by Arnould. (Ex. 1002, ¶¶235-37).

iv. <u>Claim 37[b]: the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.</u>

Arnould describes a bone plate comprising screw 30 that is angularly inserted into hole 25 relative to the plate body:

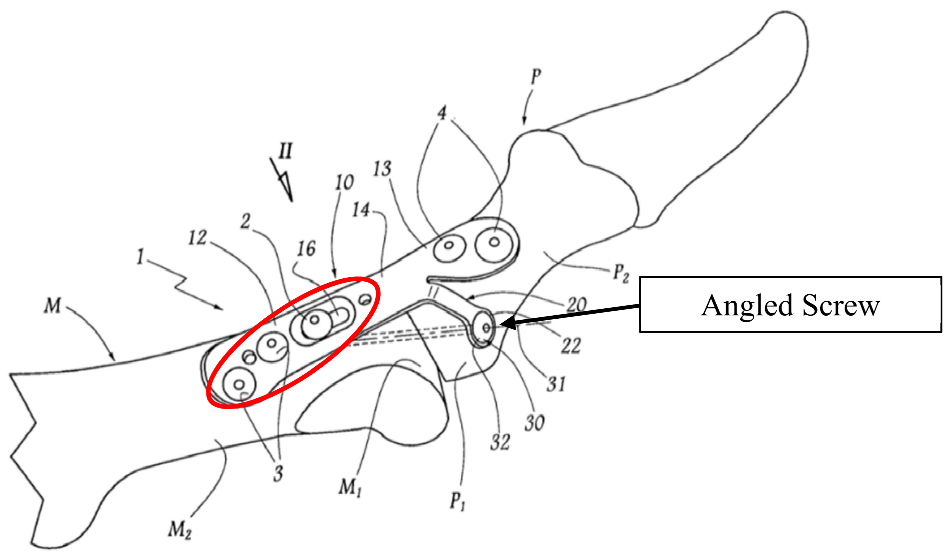


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶¶32-34). Screws 3 and 4 are inserted into respective holes 15_1-15_4, and are configured to secure the plate body to the metatarsal and phalanx. (Ex. 1006, ¶¶32-34). A POSITA looking at Figure 1 would understand that screw 30 is angled relative to screws 3 and 4. (Ex. 1002, ¶238).

Thus, a POSITA would find this element is taught by Arnould. (Ex. 1002, ¶239).

v. <u>Claim 38: The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.</u>

Arnould discloses partially affixing the bone plate so that surgeon can correctly place the plate before the plate is permanently affixed. (Ex. 1006, ¶31). While Arnould does not explicitly describe the use of k-wires to temporarily hold

the plate in place while the screws are inserted, the figures show pin holes that are used to temporarily secure the plate with k-wires during the implantation process:

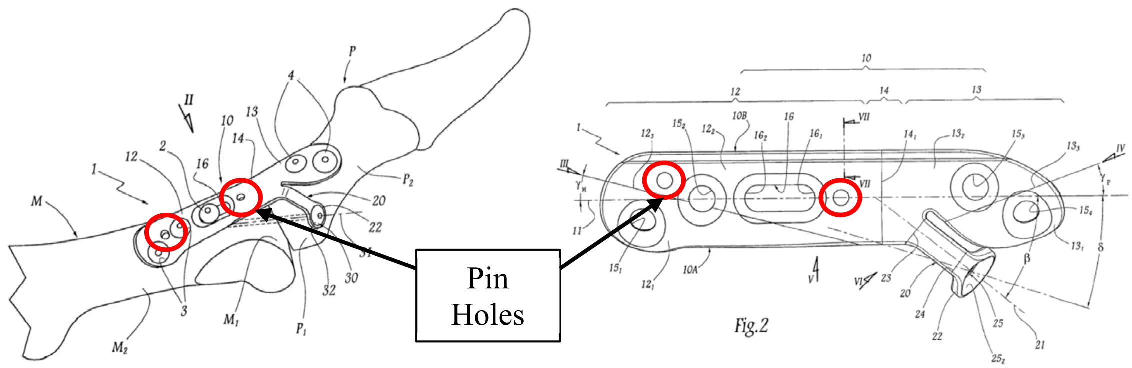


Fig.1

(Ex. 1006, FIGS. 1, 2 (annotated); Ex. 1002, ¶240). K-wires are commonly used for temporary placement and immobilization of bone plates so that the surgeon can correctly position and align a plate. (Ex. 1002, ¶240).

Thus, a POSITA would find this claim obvious in view of Arnould. (Ex. 1002, ¶241).

To the extent that Arnould does not render this element obvious, a POSITA would have readily looked to Zahiri. (Ex. 1002, ¶242). Zahiri explicitly discloses additional pins that "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). Figure 8 shows the location of these pin holes:

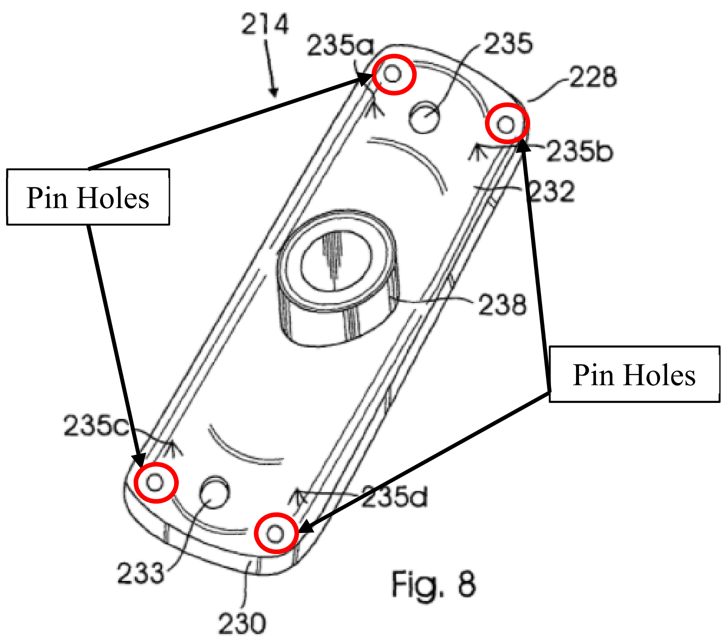


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* Ex. 1002, ¶242). Additionally, after "the lag screw 12 is settled inside of the epiphysis 8 the four pins are pulled out, and a medium size screw 33a is pressed and turned through the hole [2]33 of the plate [2]14 and into the bone diaphyseal segment." (Ex. 1007, 7:63-8:11). Since Arnould describes temporarily securing the plate, a POSITA would be motivated to utilize the pin holes in Zahiri to ensure proper placement and alignment of the plate during implantation. (Ex. 1002, ¶242). Use of temporary fixation pins was common at the time of invention, and would have been readily utilized by a POSITA given the explicit disclosure in Zahiri and the desire to temporarily secure Arnold's plate. (*Id.*).

Thus, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1002, ¶243).

vi. <u>Claim 39: The method of claim 32, wherein the joint is one of the anatomical joints of the human body in the foot or hand.</u>

Arnould discloses a bone plate for arthrodesis of the metatarsophalangeal joint which is a joint within the foot:

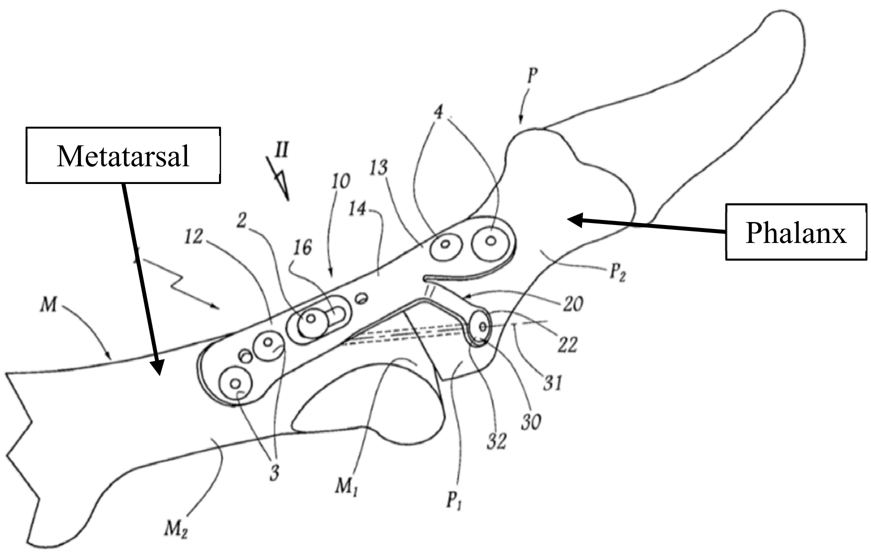


Fig. 1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶5). Arnould specifically states that "Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." (Ex. 1006, ¶11). A POSITA would understand that the metatarsal and phalanx are bones in the foot. (Ex. 1002, ¶244).

Thus, a POSITA would find that this claim is taught by Arnould. (Ex. 1002, ¶245).

IX. CLAIM APPENDIX OF THE CHALLENGED CLAIMS

[32pre]	A method of fusing a joint, the method comprising:
[32a]	spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;
[32b]	inserting a first fixation member through the first hole of the plate and into the first bone of the joint;
[32c]	inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and
[32d]	inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone and
[32e]	a head of the third fixation member is seated in the third hole,
[32f]	the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,
[32g]	wherein the third fixation member is the only fixation member extending across the joint.
[33]	The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.
[34]	The method of claim 32, wherein the first and second holes are locking holes.

Trials@uspto.gov
571-272-7822

Paper 8
Date: August 12, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00487
Patent 9,078,713 B2

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and
MICHAEL A. VALEK, *Administrative Patent Judges.*

VALEK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Regarding elements [32e] and [32f], Patent Owner argues that Petitioner's rationale for combining Zahiri's seated lag screw arrangement with Arnould is insufficient. *See* Prelim. Resp. 42–47. Patent Owner's arguments are unavailing on the current record. As an initial matter, the Petition relies on Zahiri only "[t]o the extent that Arnould is found to not explicitly disclose" elements [32e] and [32f]. Pet. 67, 70. As explained above, on the current record, Petitioner has shown that the plate depicted in Arnould Figures 1 and 4 teaches a third fixation member (screw 30) seated in a third hole (hole 25) and extending through at thickness of the plate as recited in elements [32e] and [32f]. Thus, on the current record, Petitioner has met its burden to show the prior art teaches or suggests these elements even without combining the additional teachings in Zahiri.

Regarding Petitioner's alternative theory that it would have been obvious to combine Zahiri's lag screw arrangement with Arnould's plate, the Petition explains, supported by the testimony of Mr. Sherman, that a POSITA would have looked to Zahiri "to improve the placement" and "the integrity of the angled fixation screw." Pet. 67–68, 70 (citing Ex. 1002 ¶¶ 216, 221). While we agree with Patent Owner that Petitioner's reasoning for combining the references lacks detail, we nevertheless determine it is sufficient to meet Petitioner's burden at this stage of the proceeding. Patent Owner will have the opportunity to present evidence and argument in its Response, and these issues in particular would benefit from further development at trial.

Petitioner's showing for dependent claims 33 and 36–39 is also sufficient for institution. *See* Pet. 73–85 (citing evidence). At this stage, Patent Owner does not present any arguments against Petitioner's showing

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner,

v.

Stryker European Operations Holdings LLC
Patent Owner.

Case No. 2022-00487
Patent No. 9,708,713

PATENT OWNER'S RESPONSE

best reference. I just said a person of ordinary skill in the art ***could*** look to the prior art encountered in Zahiri." (EX2009, 132:13-22). Mr. Sherman even contradicted himself, stating that "[i]f I said Zahiri is an improved system, I misspoke because Zahiri is focused at – not focused at arthrodesis." (*Id.*, 134:9-21). In short, Mr. Sherman relied on Zahiri because his counsel gave him Zahiri to pick and choose selected elements to cobble together with Slater, not because a POSITA would have been motivated to combine these two very disparate references. Petitioner's obviousness argument fails.

D. Ground 4: The Petition Fails to Demonstrate that Arnould in View of Zahiri Renders Obvious Claims 32, 33, 36-39

For Ground 4, Petitioner argues that claims 32, 33, and 36-39 are obvious in view of the combination of Arnould and Zahiri. As discussed above, since claims 33 and 36-39 depend from independent claim 32, the arguments for claim 32 equally apply to claims 33 and 36-39.

1. No Motivation to Combine Arnould with Zahiri

Petitioner fails to present sufficient evidence and argument that a POSITA would have been motivated to combine Arnould and Zahiri in a manner that satisfies the claimed method steps. *See United Indus. Corp. v. Susan McKnight, Inc.*, IPR2017-01687, Paper 31 at 10-11 (P.T.A.B. Jan. 22, 2019) (citing *ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1363 (Fed. Cir. 2018)). The Institution

Decision acknowledged that "we agree with Patent Owner that Petitioner's reasoning for combining the references lacks detail." (Paper 8, 32).

a. Arnould and Zahiri Are Not Analogous Art

Petitioner incorrectly concludes that Arnould and Zahiri are in analogous fields of art because "Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone or across a fracture" and "[a] POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture." (Pet., 57). But as described above, Zahiri is directed to an odd angle internal fixation device, not a bone plate. (*See supra*, Section V.C.1; EX2005, ¶¶70-76, 166; EX2007, ¶¶46-56).

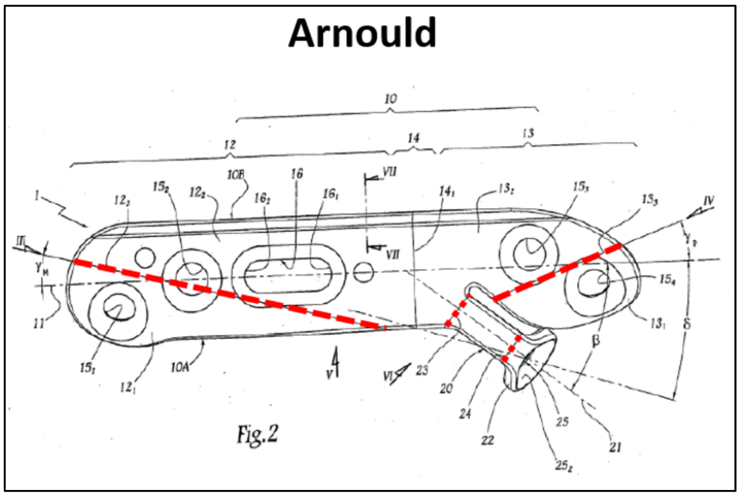
Setting aside that Zahiri is not a "bone plate" as claimed, Petitioner's generic statement that "a POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture" is insufficient to establish that Arnould and Zahiri are directed to analogous art. (EX2005, ¶¶63-76). Arnould discloses a thin bone plate specifically designed to span the metarsaophalangeal joint to immobilize the metatarsal and the phalanx, to conform to the anatomical contours of the first metatarsal and phalanx, and to allow the surgeon to select an angle for a long screw that best captures the epiphyseal zones

of both the first metatarsal and the phalanx. (EX1006, ¶6). In contrast, the Zahiri device is a compact, rigid guide plate specifically designed to guide a lag screw across a fracture of the proximal humerus (a far larger bone) at a fixed angle and to lock the lag screw in place. (EX1007, 6:30-35, 6:36-7:9, 7:15-19, 7:29-31, 7:55-62; EX2005, ¶¶71, 74, 128). The Zahiri device sits on one side of the fracture and thus cannot itself immobilize the fracture. (EX2005, ¶¶71, 125-126). A POSITA would understand that there are many practical differences between fusing an MTP joint and guiding a lag screw across a fracture of the proximal humerus. (EX2007, ¶55). Moreover, a POSITA would have understood that, contrary to Petitioner's suggestion, the Arnould bone plate and the Zahiri device would not and could not be used interchangeably. (*Id.*, ¶131; EX2007, ¶55).

b. Zahiri Teaches Away from Arnould

A POSITA would not have been motivated to combine Arnould and Zahiri because Zahiri teaches away from the advantages set forth in Arnould. (EX2005, ¶¶167-176). Similar to Ground 3, Petitioner nowhere explains how Zahiri's barrel portion and lag/locking screw arrangement would be combined with the thin, dorsal-mounted MTP plate described in Arnould. As shown in annotated Figure 2 of Arnould below, the Arnould plate has an elongated body designed to straddle the MTP joint, with bending lines and curved sections to conform to the shape of the

upper surfaces of the metatarsal and phalanx and to allow the surgeon to modify the angle of dorsiflexion to take into account "the bone resections and the general morphology of the patient's bones, as well as his or her footwear habits and, more particularly, the height of the shoe heel." (EX1006, ¶¶14-18, 38).



(*Id.*, Fig. 2)

The Arnould plate body includes through-holes to allow for the fixation of the plate body to the metatarsal and the phalanx. (*Id.*, ¶21). Arnould also features a leg that extends from and bends down relative to the phalangeal portion of the plate body, and is shaped to wrap around the phalangeal epiphysis "as close as possible to the bone material." (*Id.*, ¶23). The leg is provided with a through hole for receiving a long screw, the direction of insertion which "is ***chosen by the surgeon*** so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1." (*Id.*, ¶32).

Zahiri, on the other hand, is a rigid guide plate that does not allow a surgeon to conform the plate to the anatomy of a patient's bones. As Mr. Sherman admitted, Zahiri's device is not pliable like the Arnould plate. (EX2009, 158:7-13 ("Q. Could a surgeon use plate benders to modify Zahiri? … A. I don't know that Zahiri addresses it, but probably not. It just generally appears to be too short of a space and intended to be on a flat surface as well.")).

Zahiri features a short barrel mated with a specially designed lag screw with a locking screw on top to lock the lag screw at a fixed angle. (EX1007, 7:55-62). Due to the fixed angle design of Zahiri's device, the surgeon cannot select the angle of insertion of the lag screw to adapt to the individualized needs of a particular patient, thus eliminating one of the advantages of the Arnould plate. (EX2005, ¶176). Moreover, the rigid geometry of the barrel and guide plate of Zahiri would be incompatible with the bendable leg of the Arnould plate and would certainly not allow the Arnould leg to wrap around the phalangeal epiphysis as contemplated. (*Id.*, ¶¶168-170).

Petitioner nevertheless states that "a POSITA would look to Zahiri when making improvements to Arnould's plate." (Pet., 59). But Petitioner nowhere explains what "improvements" are being suggested or why such purported improvements are needed in the Arnould plate. It is therefore unclear how Zahiri

can be classified as an "improve[d]" system, as Petitioner suggests. In fact, Mr. Sherman apparently agrees that Zahiri is not an "improved" system. (EX2009, 134:14-19). There is simply no support for Petitioner's conclusory contention that a POSITA would look to Zahiri to modify Arnould.

c. Petitioner's Combination is Based on Improper Hindsight

Petitioner's incorporation of Zahiri's "temporary guide pins" and "temporary pin holes" into the Arnould plate is solely based on impermissible hindsight. (Pet., 61). As discussed *supra*, however, Zahiri's "pin holes" and "four tips" were designed to solve the problem of torqueing, or spinning of the Zahiri device on the humeral cortex as the lag screw was advanced into the epiphysis. (EX1007, 1:55-61, 3:41-44, 5:52-59, Fig. 3; *see supra,* Section V.C.1.c.).

Arnould's disclosure renders unnecessary Zahiri's "known technique for improving plate alignment during implantation." (Pet., 62). As an initial matter, the Arnould plate is not at risk for unwanted torqueing or spinning because (1) it is contoured to the metatarsal and phalanx, with a leg wrapping around the phalangeal epiphysis, and (2) Arnould discloses a way to align the plate prior to insertion of the cross screw by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.*, ¶31; EX2007, ¶¶65, 44-45). The partial insertion

of screw 2 into oblong hole 16 serves to "partially immobilize" the plate body 10. Screw 2 is not a temporary fixation member, as it is later "completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M." (EX1006, ¶¶31-33, 8). As such, a POSITA would understand that proper alignment and "partial immobilization" during implantation is obtained in Arnould ***without*** the need for Zahiri's temporary fixation features. (EX2007, ¶¶63-66, 44-45; EX2005, ¶182).

d. No Reasonable Expectation of Success

Furthermore, nowhere does the Petition provide an analysis directed to a POSITA's reasonable expectation of success in combining the Zahiri lag screw configuration with Arnould. As discussed above, adding the bulky Zahiri barrel to Arnould's thin, bendable leg simply would not work. (EX2005, ¶¶177-178). Petitioner has not shown "that the skilled artisan would have had a reasonable expectation of successfully achieving the claimed invention from the combination." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4d 1331, 1344 (Fed. Cir. 2021); *see also Intelligent Bio-Sys.*, 821 F.3d at 1367-68.

2. Arnould and Zahiri Do Not Render Obvious Claim 32

With respect to independent claim 32, Petitioner argues that "Arnould discloses [claim elements [32pre]-[32c]]," "a POSITA would find [claim element

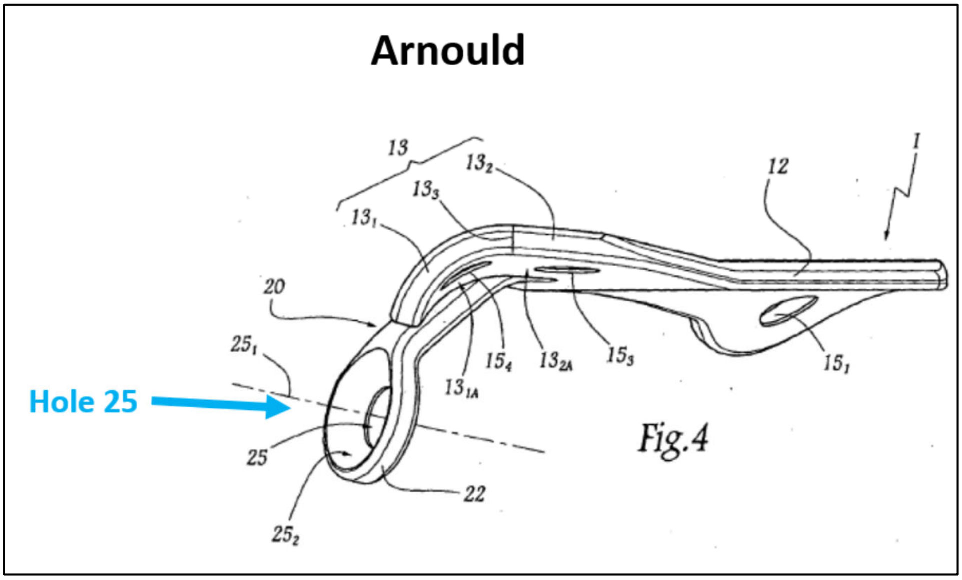
[32d-g]] disclosed by Arnould," and, "[t]o the extent that Arnould is found to not explicitly disclose this element … a POSITA would find [claim elements [32e]-[32g]] obvious in view of Arnould and Zahiri." (Pet., 62-73). However, Arnould does not disclose each and every claimed method step and, as described above, there is no motivation to combine Zahiri with Arnould with respect to the missing elements.

a. Claim Element [32f]

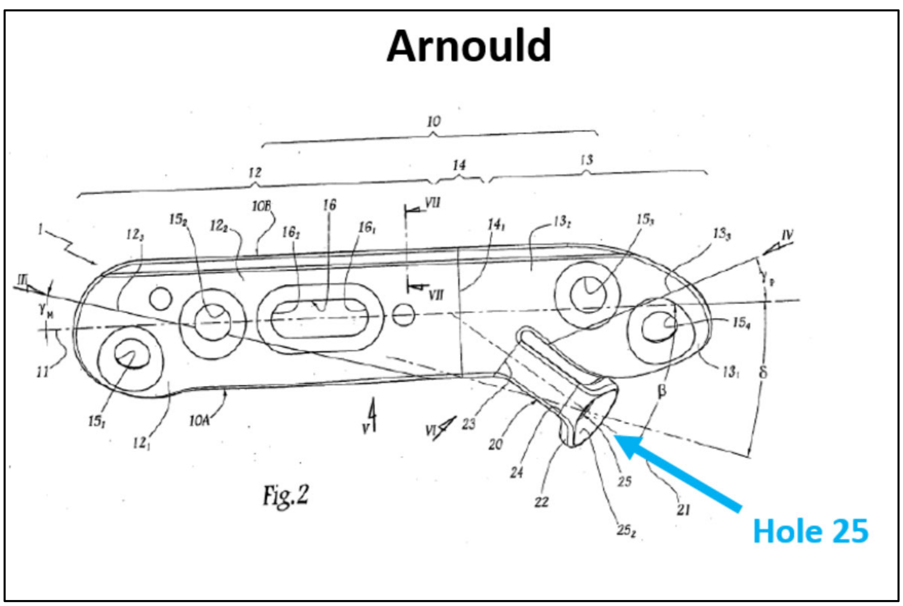
Arnould does not disclose a "***third hole being angled*** relative to a longitudinal axis of the plate ***through a thickness of the plate***." (EX1001, cl. 32). Petitioner contends that Arnould describes a screw hole 25 configured "such that the screw 30 forms a non-zero angle in relation to the longitudinal axis of the plate body, concluding that "the trajectory of the third fixation member, and therefore the third hole, is angled relative to the longitudinal axis of the plate." (Pet., 69).

However, while the trajectory of screw 30 may be angled, it does not follow that hole 25 is necessarily angled. (EX2005, ¶186). Rather, the size and shape of the screw head may permit the screw to be placed at different trajectories regardless of whether the hole is angled. (*Id.*, ¶¶186-187). As shown in Figure 4, screw hole 25 is not angled "through a thickness of the plate," nor would a POSITA consider

screw hole 25 to be angled "through a thickness of the plate" as required by the claim. (EX2005, ¶¶188-189).



(EX1006, Fig. 4). Rather, screw hole 25 appears to have the same geometry as screw holes 15_1, 15_2, 15_3, and 15_4. (*Id.*, Figs. 1, 2, 4-6; EX2005, ¶188).



temporarily secure the plate with k-wires during the implantation process," the holes that Petitioner refers to are never discussed in Arnould. (*Id.*, 59, 83; EX2005, ¶203).

Moreover, as discussed above, a POSITA would not have been motivated to combine the temporary pins or pin holes of Zahiri with Arnould because Arnould expressly describes a procedure for stabilizing its plate that ***negates*** the need for using temporary fixation pins in specially designed pin holes. (EX2005, ¶204; EX2007, ¶65; Section V.D.1.c). As such, Petitioner's obviousness argument must fail.

E. Ground 5: The Petition Fails to Demonstrate that Arnould in View of Zahiri and Myerson Renders Obvious Claims 34 and 35

Petitioner contends that dependent claims 34 and 35 are obvious in view of the combination of Arnould, Zahiri, and Myerson. (Pet., 86-88). For the reasons discussed above in Ground 4 regarding independent claim 32, Petitioner's obviousness argument must fail.

Additionally, Petitioner has not demonstrated a motivation to combine Arnould, Zahiri, and Myerson to render obvious claims 34 and 35. (EX2005, ¶¶209-212). Instead, Petitioner relies on its flawed motivation to combine analysis of Arnould and Zahiri from Ground 4 and separately contends that a POSITA would be motivated to combine the teachings of Myerson to modify the Arnould bone plate. (Pet., 86). However, Petitioner never demonstrates that a POSITA would have been

motivated to combine all three references together. In *Apple Inc. v. MPH Techs. Oy*, 2021-1355, 2022 WL 4103286 (Fed. Cir. Sept. 8, 2022), the Federal Circuit explained that it "[has] reversed Board decisions that found a motivation to combine where the petitioner presented only threadbare arguments to support its combination, let alone where a party entirely failed to address one of the references it sought to combine." *See, e.g., TQ Delta*, 942 F.3d at 1359.

Petitioner's Ground 5 arguments must fail.

VI. CONCLUSION

Petitioner has failed to demonstrate that any of the Challenged Claims (claims 32-39 of the '713 patent) is unpatentable. For at least the reasons set forth above, the Board should uphold the patentability of challenged claims 32-39 of the '713 patent.

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00487
U.S. PATENT NO. 9,078,713

PETITIONER'S REPLY IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
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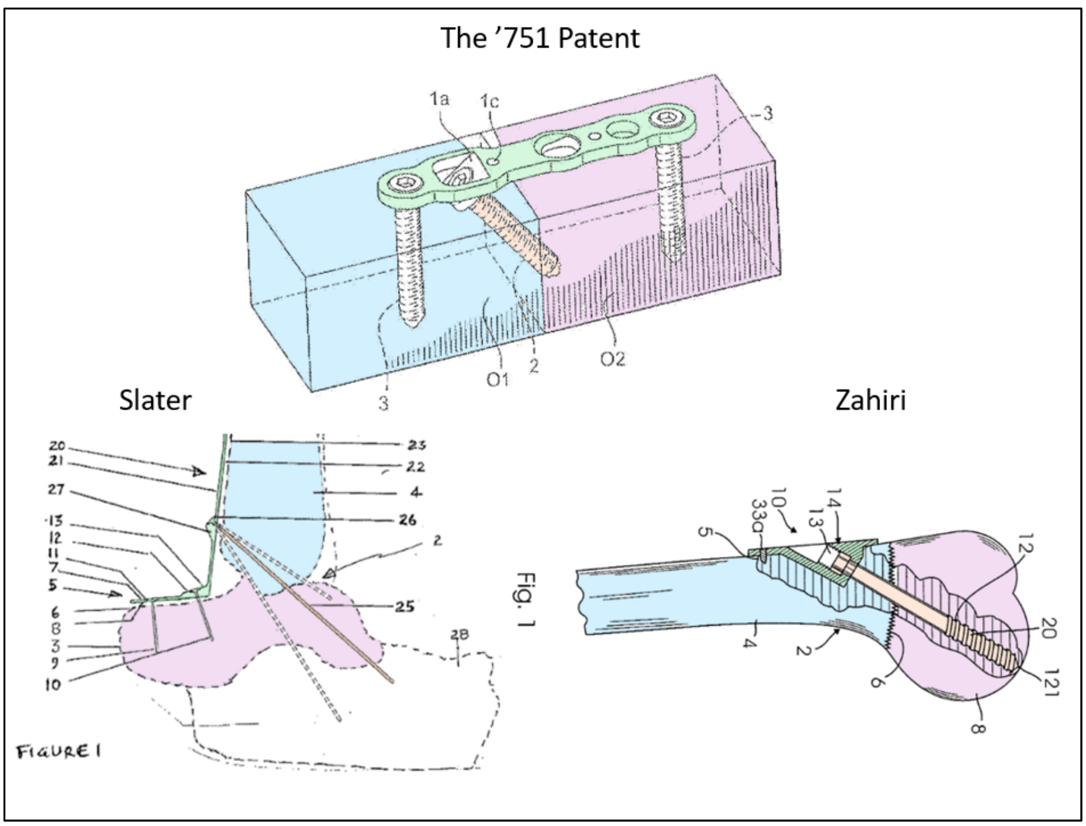
(refusal to answer whether bone plates can be fixed entirely on one side of a fracture or joint).

Zahiri also need not describe a "bone plate" to be analogous art. *Bigio* explains a reference is analogous art to the claimed invention if: (1) it is in the same field of endeavor (even if it addresses a different problem); or (2) it is reasonably pertinent to the problem faced by the inventor. *Id.* Like the '751 Patent, both Slater and Zahiri disclose plates configured to fuse bones with an angled screw that crosses a fracture or joint for fusion:



Ex. 1001, Fig. 1; Ex. 1004, Fig. 1; Ex. 1007, Fig. 1. These similarities readily satisfy the *Bigio* requirements of "analogous art."

own expert admits Slater discloses countersunk and seated screw holes, PO's assertion that a POSITA would not look to similar type screw arrangements (such as in Zahiri) to improve the integrity of the bone plate falls flat. A POSITA would readily look to the dimensions and structure of Zahiri's angled screw formation to enhance the effectiveness and stability of its own angled screw formation particularly when structured to contact two bones. Petition, 44-45. Slater illustrates its cross-bone screw formation terminating in the second bone, and describes the importance of ensuring the angle of the cross-joint screw is oriented for the particular needs of the patient. *Id.*, 44. Incorporating Zahiri's configuration is not contrary to Slater's disclosure allowing a wide range of angles in the cross-joint screw because Zahiri discloses providing plates with a variety of angles in a kit so the surgeon can choose the plate that will maximize fixation based on the particular needs of the patient. Ex. 1007, 3:59-64, 9:1-4. This is consistent with Slater's principle of operation because, as Slater explains, "[t]he invention further relates to a kit including a selection of ankle fusion plates and a selection of fasteners for fixation of the ankle plate in a prescribed manner such that orientation of the screws provide optimal compression and therefore mechanical advantage." Ex. 1004, 2:12-15; *id.*,

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was unwilling to testify what "seated" meant to him. Ex. 1015, 129:25-130:14, 132:6-133:17.

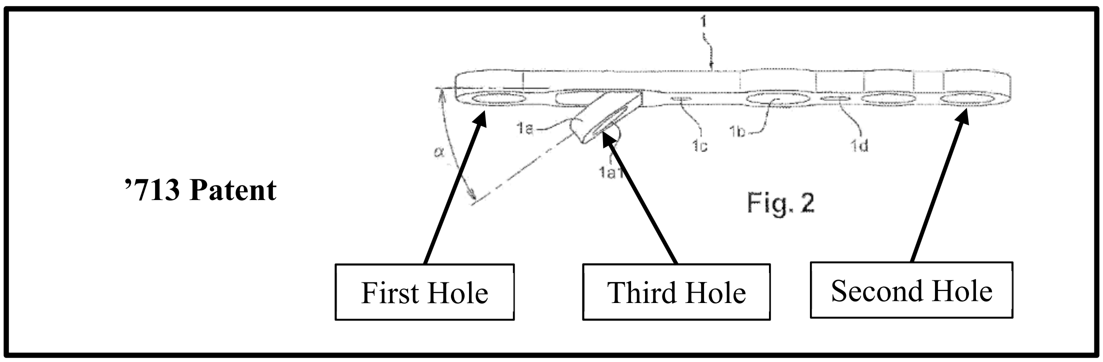
humerus bone. But PO ignores Zahiri's teachings are not limited to one specific application, and that both references recognize the need to stabilize a bone plate during implantation of a lag screw. Ex. 1007, 1:51-57; Ex. 1004, 3:21-25. In light of the extensive knowledge in the art regarding temporary fixation members and pin holes, a POSITA would reasonably expect incorporating such a feature into Slater would be successful, as detailed in the Petition. Petition, 45-47, 56; Ex. 1002, ¶¶164-167, 187.

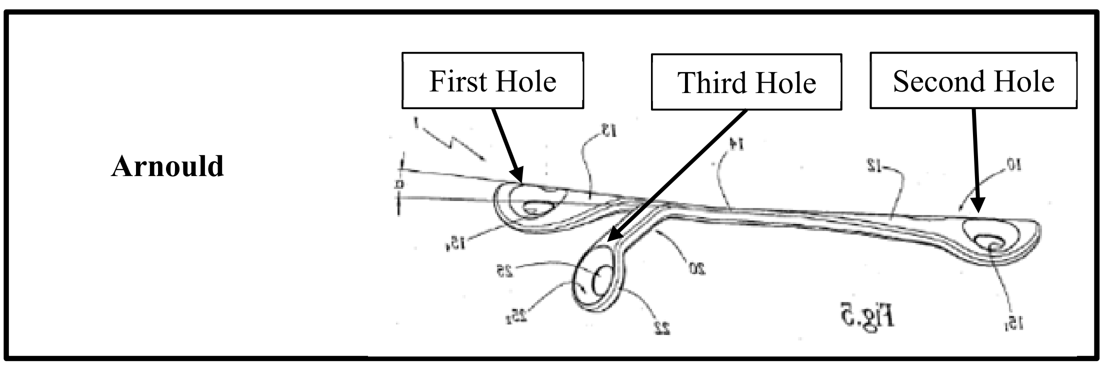
Finally, while PO argues Petitioner is combining distinct embodiments from Zahiri, PO fails to explain—at all—how this is improper with respect to the pin holes that are included on the various plates. The pin holes shown in Zahiri's Figures 2 and 8 are the same: "[t]he same small holes and tips are also used with this embodiment, and since they assemble and function the same as previously described, and the description thereof will not be repeated." Ex. 1007, 8:41-44.

VI. GROUND 4: ARNOULD IN VIEW OF ZAHIRI[6]

A. Claim 32

PO's argument that Arnould allegedly fails to disclose the third hole angled relative to the longitudinal axis (32[f]) is nonsensical. As illustrated below, the third hole of Arnould is nearly identical to the only third hole depicted in the '713 Patent:





Ex. 1001, Fig. 2 (annotated); Ex. 1006, Fig. 5 (annotated). The surface of Arnould's third hole, like the third hole in the '713 Patent, is not in the same plane as the main

6 PO does not address claim 39 with respect to Ground 4, so this claim is not independently addressed again in this paper.

body of the Arnould plate, but rather angled relative to the longitudinal axis of the plate, just as the claim requires.

PO strangely argues hole 25 is not an "angled hole" because it has the same shape and geometry of the other holes shown on Arnould's plate. POR, 59. This cannot be squared with the disclosure of the '713 Patent that illustrates a single angled hole on a tab below the surface of the bone plate that has the same shape and geometry of the other holes depicted. Moreover, PO seems to suggest the hole itself has to have some angular geometry, but the claim simply reads that the "third hole is angled relative to the longitudinal axis" of the bone plate. Ex. 1001, cl. 1.

Arnould's third hole identified in the Petition meets this requirement without turning to the disclosure of Zahiri, which renders PO's challenges to the combination with Zahiri irrelevant. Nevertheless, as detailed in the Petition, a POSITA would be motivated to improve the integrity of hole 25 while still ensuring flexibility of the screw trajectory because of pliable leg 20. Ex. 1007, [0023]; *see also* Petition, 67 (surgeons able to modify angle δ relative to the longitudinal axis). In addition, "[a] POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw," such as by having the screw 30 of Arnould fully seated. Petition, 68.

B. Claim 36

PO's argument regarding claim 36 focuses on its illogical interpretation of the

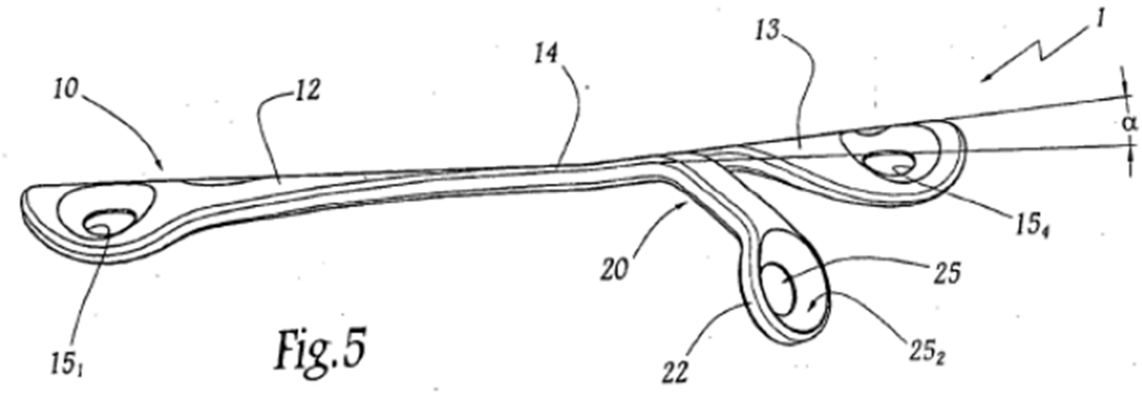


Fig.5

Ex. 1006, Figs. 4, 5.

D. Claim 38

With respect to the pin holes of claim 38, PO does not dispute Arnould and Zahiri teach such holes. POR, 65-66. PO claims there would be no need to use Arnould's pin holes as temporary fixation holes because "Arnould expressly describes a procedure for stabilizing its plate that negates the need for using temporary fixation pins in specially designed pin holes." POR, 66. However, the oblong holes Dr. Holmes and Mr. Leinsing refer to allow for movement of the plate along the longitudinal axis (direction 11 shown in Figure 2), not stabilization of the plate. Given Arnould includes the smaller holes indicates k-wires or other temporary fixation devices would be used and would assist with placement. *See* Petition, 83-84.

PO's arguments on improper hindsight fall similarly flat. Arnould itself discloses pin holes. Petition, 59-61. For additional details regarding these pin holes,

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

Case No. IPR2022-00487

U.S. Patent No. 9,708,713

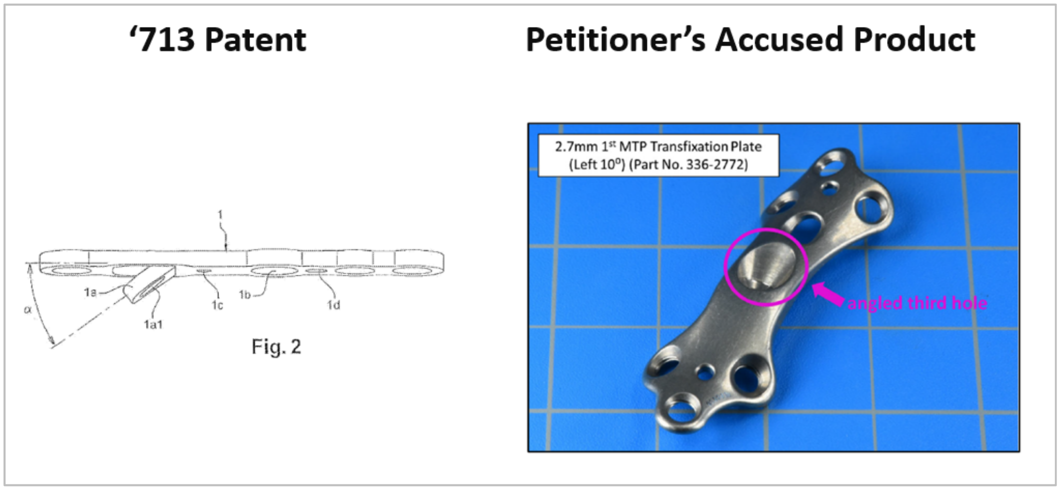
PATENT OWNER'S SUR-REPLY

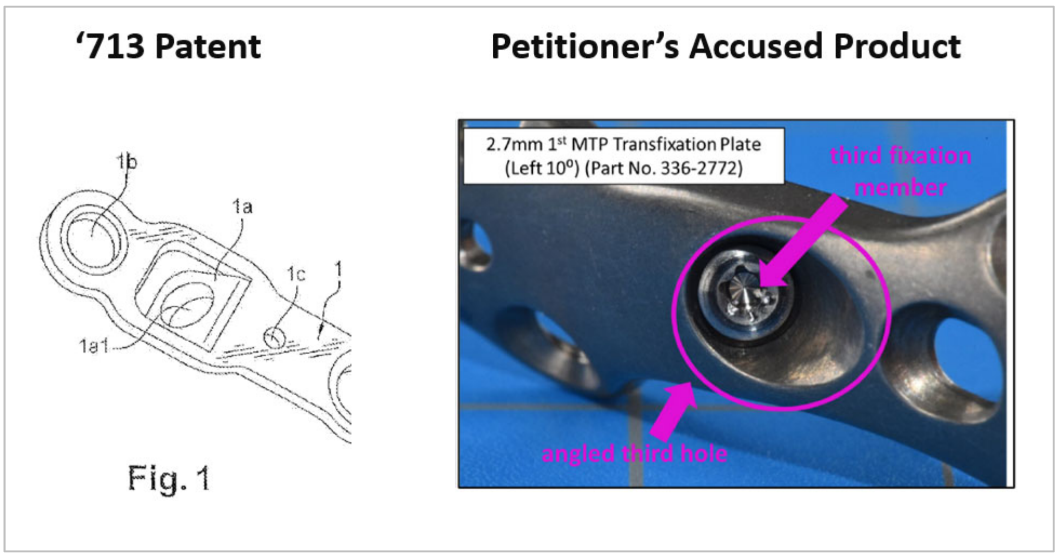
require[s] Petitioner to show not only that a [POSITA] could have combined the references in the proposed manner, but that a [POSITA] would have had a reason to combine [the prior art].").

VI. GROUND 4

A. Claim 32

Mr. Sherman provided no rebuttal to Mr. Leinsing's explanation of why hole 25 is not an "angled hole" as claimed. (EX2005, ¶¶185-191). Instead, Petitioner improperly confines the claim to the illustrated embodiment in the 713 patent figures. *Lowe v. ShieldMark, Inc.*, No. 2021-2164, 2022 WL 636100, at *6 (Fed. Cir. Mar. 4, 2022) ("[E]very figure in the specification depicts tape with shoulders. Importantly, however, that does not necessarily require us to narrowly limit the claimed invention to those figures. . . . the specification *describes* various embodiments of the tape, several without shoulders."). The second embodiment described in the 713 patent, the "angled hole," is not shown in the figures. (EX1001, 1:45-46; 2:8-10). As shown below, an angled tab differs from an "angled hole."





(EX1001, Fig. 1, Fig. 2; EX2024, 29)

As discussed in the POR, a POSITA would not have looked to Zahiri for a "way to improve the integrity of the angled fixation screw," nor does Petitioner provide any evidence supporting such a conclusion. (POR, 37-41, 61-63). Mr. Leinsing provided unrebutted testimony describing why a POSITA would not have been motivated to combine Arnould and Zahiri, why Arnould teaches away from

Trials@uspto.gov
571-272-7822

Paper No. 36
Entered: July 13, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00487 (Patent 9,078,713 B2)[1]
IPR2022-00488 (Patent 10,993,751 B1)

Record of Oral Hearing
Held: May 11, 2023

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and
MICHAEL A. VALEK, *Administrative Patent Judges*.

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[1] This Record of Oral Hearing is entered in both cases. The parties are not authorized to use this style heading for any subsequent papers.

sufficient for those claims.

JUDGE VALEK: Now, is that different for the 488 proceeding?

MS. BEANE: In the 488 proceeding, there are –- I actually -– I think I have to take one step back –- I believe that Claim 38 of the 487 proceeding -– the '713 Patent –- relates to the guide pin holes and we've said that Arnould discloses those holes with the knowledge of a POSITA, but I do think that we rely more on Zahiri for that claim; and the same would be true then of the '751 Patent with respect to the guide pin holes, we rely more on Zahiri; and as well, Claims 11 and 17 of the '751 Patent in the 488 proceeding, specifically detail the geometry of the third and the fourth holes, and while we believe that Arnould shows that in the pictures, there's no description of that in the specification of Arnould; and so, we do rely on Zahiri for that as well, and that relates to Claims 11 and 17 of the '751 Patent, 488 proceeding.

Okay. So, I want to turn to Slide 60 to discuss the combination of Arnould and Zahiri; and again, Mr. Sherman explains that the bone plate and screw interface is vitally important to ensure proper fixation of the plate, and I think when you read Arnould, you understand even more as to why that's the case because in our Arnould it's structured to have the majority of the compression stress actually felt in the head of that cross-joint screw itself; and so, ensuring that that cross-joint screw head is fixed properly to the plate and has the strongest combination and interface is vitally important in the context of Arnould; and as Mr. Sherman explains, you would then look to Zahiri to ensure that that's the strongest mechanism possible to improve the placement of the angled fixation screw.

Now, we also discussed with Your Honors -– if you could go to Slide

no evidence to support this limitation. They just dealt with the angled portion. With respect –-

JUDGE VALEK: What about the picture, Counsel? So, I hear what you're saying, that they didn't say it in words; but –- you know –- a picture's worth a thousand words and the picture seems to show a hole that's between –- a third hole between –- the other two.

MS. HWANG: -- Well, we –-

JUDGE VALEK: Why isn't that enough for them to meet their burden?

MS. HWANG: -- Let's to go Slide 115 and we do want to talk a little bit –- well –- I'm sorry –- go to 188, when we look at Arnould. I want to use this hand analogy that Petitioner brought up and discussed in the deposition of Mr. Leinsing and also in their papers. So, if my hand is located similar to where the leg of Arnould is with the hole, my hand is not between my head and my feet; actually, it's like off to the side and it's a little bit above; and so, when you look at that, look at what they've circled as the first hole –- or -– first holes –- and if you imagine that leg being straightened, that's not between the first hole and the second hole. The testimony from our expert is not that just because it's plunging downward, that's why it's not between; he specifically said the angled tab is not offset –- I'm sorry –- that this is offset, just like the angled tab in our picture of the '751 Patent, that's not offset and that's why it's still between. This one is offset, it's offset and it's actually the –- if you were to do a central axis going through that hole 25, it would never intersect with the plate longitudinal axis, it would be almost like askew line. That's not true with respect to our preferred embodiments; so, we're certainly not reading out our preferred embodiment.

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

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CASE IPR2022-00487
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DECLARATION OF MICHAEL SHERMAN

33. I have kept these considerations in mind when offering the opinions below regarding combinability, as well as when interpreting the scope and content of the prior art.

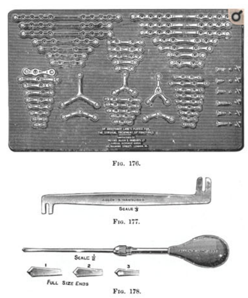
IV. OVERVIEW OF THE TECHNOLOGY

34. Metallic bone plates were first introduced in orthopedics for fracture fixation well over 100 years ago in 1895 by Sir William Arbuthnot Lane:

Clin Orthop Relat Res. 2009 Aug; 467(8): 1939–1943.
Published online 2009 May 6. doi: 10.1007/s11999-009-0861-3

Fig. 176–178

<< Prev Fig. 176–178 Next >>



Lane's set of plates and instruments is shown. (From Lane WA. *The Operative Treatment of Fractures*, 2nd ed. London, England: The Medical Publishing Company, Ltd; 1914; photograph courtesy of Library, College of Physicians of Philadelphia.)

H.K. Uhthoff et al.: Internal plating of fractures

Fig. 1. Lane's plate abandoned because of corrosion (1895). (From Bechtol CO, Fergusson AB, Laing PE. Metals and Engineering in Bone and Joint Surgery. Williams & Wilkins; Baltimore: 1959. p. 20, with permission)

35. Lane's early work was followed by Lambotte in 1909 and then Sherman in 1912. These surgeon inventors focused on minimizing the large metallurgic reaction experienced by Lane and providing a more stable level of internal fixation. They were followed by Eggers in 1948 who recognized the need for slots in the plate to accommodate bone resorption at the abutting edges of the fracture.

Fig. 2. Lambotte's plate (1909) is thin, round, and tapered at both ends

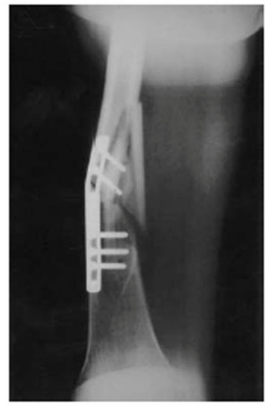


Fig. 3. Structural instability of Eggers' plate

36. In 1949 a Belgian surgeon, Robert Danis, introduced the concept of applying compression across the fracture fragments in an effort to minimize motion, increase stability and improve fracture healing. His plate, known as "coapteur" incorporated a compression bolt at one end of the plate (pictured below with the bolt on the right) which could be used to compress the fracture prior to inserting the final screw.

Fig. 4. Danis' plate (1949) called "coapteur" suppresses interfragmentary motion and increases stability of fixation through interfragmentary compression achieved by tightening the side screw

37. In the mid-1950s an orthopedic surgeon named George Bagby discovered that an offset screw in an oblong hole of a bracket could be used to create

compression across a joint. Dr. Bagby went on to develop this concept into the self-compressing bone plate:

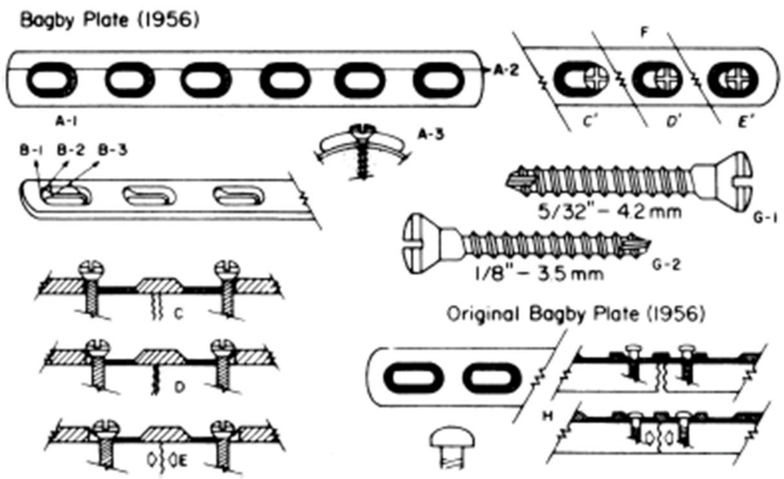
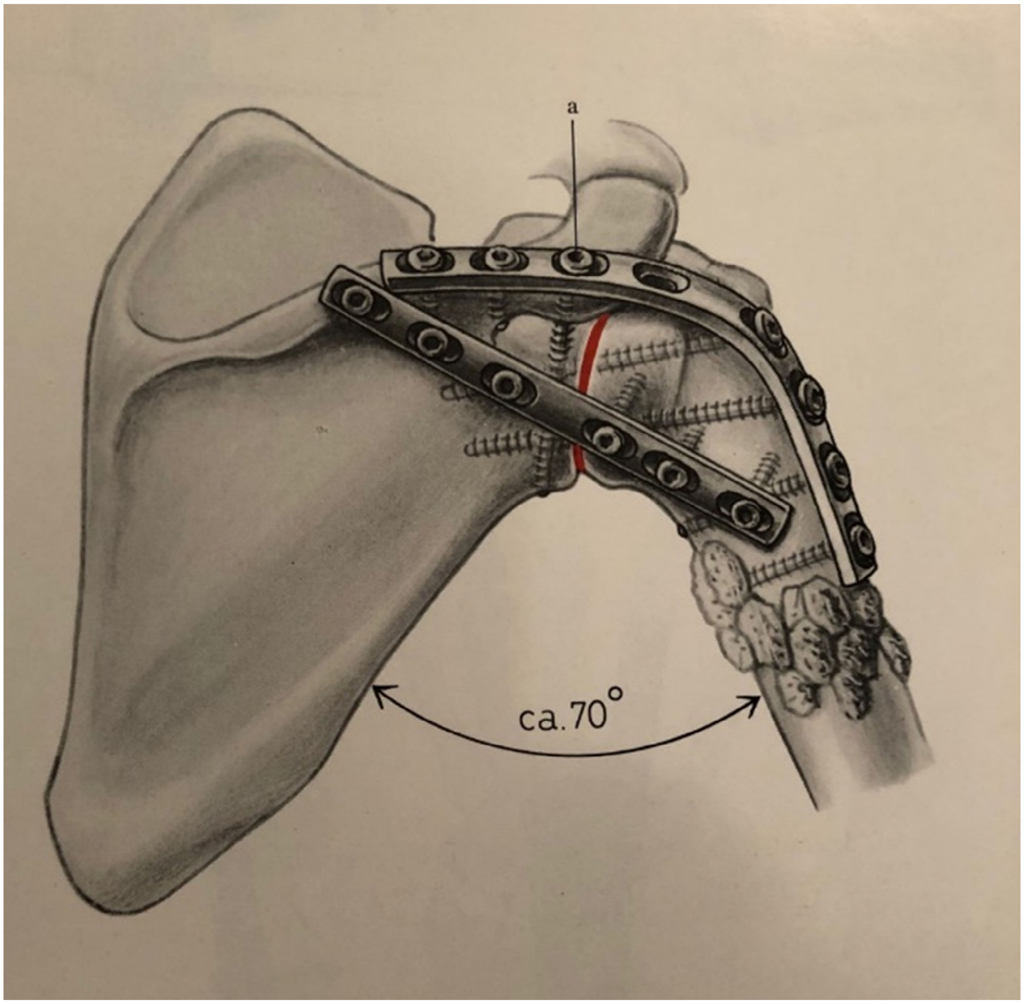


Fig. 6. Bagby and Janes' (1956) oval holes designed for interfragmentary compression during screw tightening. (From Uhthoff HK. Current Concepts of Internal Fixation of Fractures. Heidelberg: Springer-Verlag; 1980. p. 175, with permission of Springer Science and Business Media)

Dr. Bagby's use of a screw head bearing against the edge of an oblong hole during tightening to initiate lateral displacement and create compression, revolutionized plate-based fracture fixation and remains in use today.

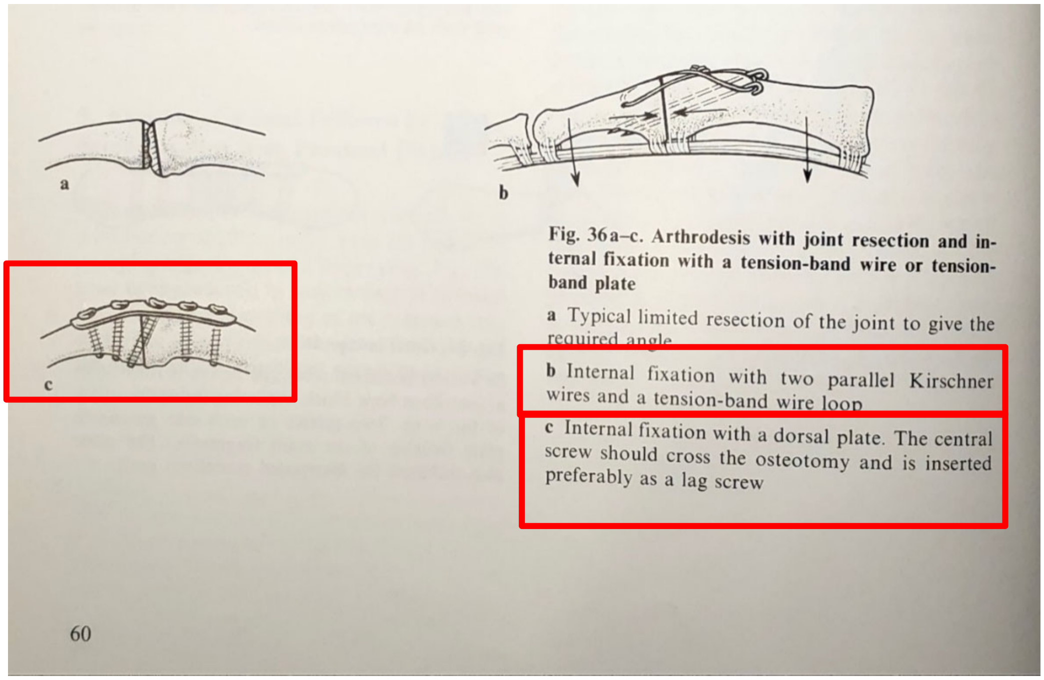
38. Plates, nails, pins and screws placed across joints to stabilize and compress the ends of bones together for the purpose of fusion, is a routine application of orthopedic hardware. The below image from "The Manual Internal Fixation," 2nd edition Springer-Verlag (1979), depicts a bone plate, contoured to accommodate the curvature of the shoulder:



The image shows a long 4.5mm DCP plate positioned over the top of the shoulder joint with 2 screws in the humerus on the outside of the shoulder joint, 3 screws in the scapula on the top of the shoulder joint and 2 screws angled through the plate passing through the humerus, across the joint (outlined in red) and into the scapula providing compression across the shoulder joint to enhance the stabilization for arthrodesis (joint fusion).

39. Below is an image from "The Small Fragment Set Manual," 2nd edition, Springer-Verlag (1982), that shows another example of a screw used through

a bone plate to compress a joint for the purposes of arthrodesis of the metacarpophalangeal joint (a joint in the hand):



a

b

c

Fig. 36a–c. Arthrodesis with joint resection and internal fixation with a tension-band wire or tension-band plate

a Typical limited resection of the joint to give the required angle

b Internal fixation with two parallel Kirschner wires and a tension-band wire loop

c Internal fixation with a dorsal plate. The central screw should cross the osteotomy and is inserted preferably as a lag screw

60

40. All of this demonstrates how bone plates, screws, pins and wires, for the purposes of both fracture fixation and joint arthrodesis, have a long history of use going back many decades prior to October 2009.

V. U.S. PATENT NO. 9,078,713

41. The ’713 Patent is titled “Orthopedic Implant in the Form of a Plate to be Fixed Between Two Bone Parts” (Ex. 1001). The ’713 Patent was filed on September 30, 2013, and issued on July 14, 2015. (Ex. 1001, Cover).

42. The ’713 Patent claims priority to foreign application FR0856694A, through intervening Application Nos. 12/918,071 and PCT/FR2009/051879. (Ex. 1001, Cover). Application No. 12/918,071 was filed on October 29, 2010,

now U.S. Pat No. 8,556,946, as a continuation application of National Stage application PCT/FR2009/051879. The National Stage application PCT/FR2009/051879 was filed on October 2, 2009, which in turn claimed prior to foreign application FR0856694A, which was filed on October 2, 2008.

43. I have been asked by counsel to use October 2, 2009 as the priority date of the ’713 Patent. The opinions I offer below regarding the prior art, the combinations set forth in my declaration, or the applicability of those combinations to certain claims of the ’713 Patent do not change whether the ’713 Patent is entitled to an October 2008 priority date, or a priority date of October 2009. I do not offer an opinion, as I have not been asked to offer such an opinion, as to the proper priority date of the ’713 Patent.

A. Summary of the ’713 Patent

44. The ’713 Patent describes and claims a method for performing arthrodesis or the surgical procedure of fusing a bone joint with a bone plate. (Ex. 1001, 1:20-22).

45. The ’713 Patent claims a “method of fusing a joint … spanning first and second bones separated by a joint with a bone plate, … wherein the third fixation member is the only fixation member extending across the joint.” (Ex. 1001, cl. 32).

46. Figure 3 of the ’713 Patent shows an exemplary application of a bone plate (1) that spans across the joint between a first bone (O1) and second bone (O2), fused by a third fixation member (2) that is the only fixation member that extends across the joint (Ex. 1001, 2:16-17 and FIG.3).:

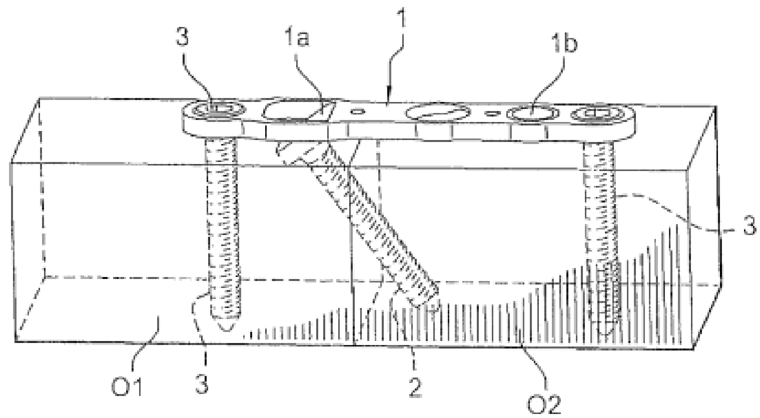


Fig. 3

47. The ’713 Patent describes how the plate, “to allow for an angular orientation of the screw 2 according to an angle between about 30° and 60°, the formation 1*a* can be formed as an angled hole.” (Ex. 1001, 2:8-17).

B. Prosecution History of the ’713 Patent

48. I have reviewed the prosecution history of the ’713 Patent, that of Application No. 14/041,706, (“the ’706 Application”). (Ex. 1003). The ’706 Application was filed September 9, 2013.

49. During the prosecution of the ’713 Patent, the Examiner rejected independent claim 32 under §102 in a Non-Final Office Action prior to allowing the application. (Ex. 1003, 132-33). Specifically, the Non-Final

bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11).

164. A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to the prior art inclusive of Zahiri when making improvements to Slater's bone plate.

165. Slater contemplates the importance of proper bone plate alignment and would guide a POSITA to incorporate the temporary pin holes disclosed by Zahiri into Slater. (Ex. 1004, 4:17-5:9). Slater specifically discloses that "[i]f an arthrodesis or ankle replacement is not properly aligned, significant gait abnormalities may result." (Ex. 1004, 4:23-25).

166. Additionally, Zahiri discloses four small holes in the corner of the bone plate intended for used with pins to temporarily hold the bone plate in place during implantation, as shown in Figure 8:

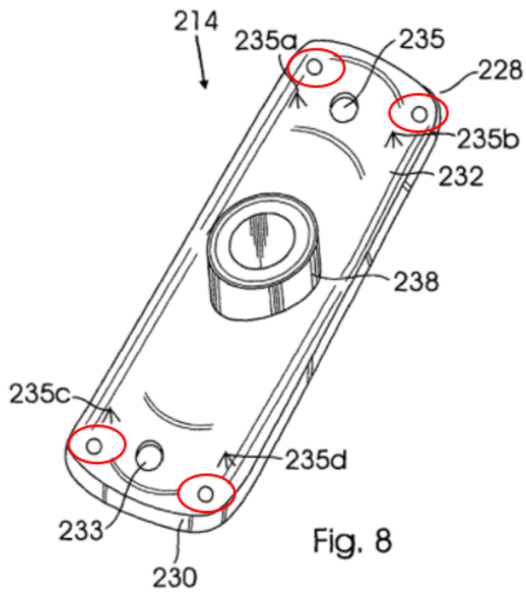


Fig. 8

(Ex. 1007, FIG. 8 (annotated)). Zahiri further states these pins "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). In other words, the four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (Ex. 1007, 3:10-18). This process ensures proper alignment during implantation and thus prevents discomfort and abnormalities. (Ex. 1007, 3:10-18).

167. Thus, a POSITA would understand that the temporary pin holes, as disclosed in Zahiri, could be implemented into Slater's bone plate to guide the plate alignment during implantation. A POSITA would further recognize that the

implantation techniques from Zahiri would support Slater's goal of reducing the risk of complications and improving the likelihood of painless, normal walking by the patient. (Ex. 1004, 5:2-3). Zahiri discloses a known technique for improving plate alignment during implantation.

168. Thus, a POSITA would be motivated to combine the teachings of Slater and Zahiri, to utilize a known prior art technique for improving the implantation of a bone plate (similar device), and obtain a similar and predictable improvement.

2. Independent Claim 32

i. [32Pre] A method of fusing a joint, the method comprising:

169. Slater discloses a bone plate configured to perform the claimed method of joint fusion, as explained above in Section VIII.A.2.i (element [32Pre]). (*See* Ex. 1004, FIG. 1, 6:14-28, 8:13-24).

ii. [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

170. Slater discloses a bone plate configured to fuse a joint between a first and second bone, wherein a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second

bone of the joint, as explained above in Section VIII.A.2.ii (element [32a]). (*See* Ex. 1004, FIG. 1, 6:14-28, 8:13-24, 13:5-18).

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

171. Slater discloses a bone plate configured for inserting a first fixation member through the first hole of the plate and into the first bone of the joint, as explained above in Section VIII.A.2.iii (element [32b]). (*See* Ex. 1004, FIG. 1, 8:13-24, 11:28-12:2).

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

172. Slater discloses a bone plate configured for inserting a second fixation member through the second hole of the plate and into the second bone of the joint, as explained above in Section VIII.A.2.iv (element [32c]). (*See* Ex. 1004, FIG. 1, 8:13-24, 11:1-16).

v. [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone

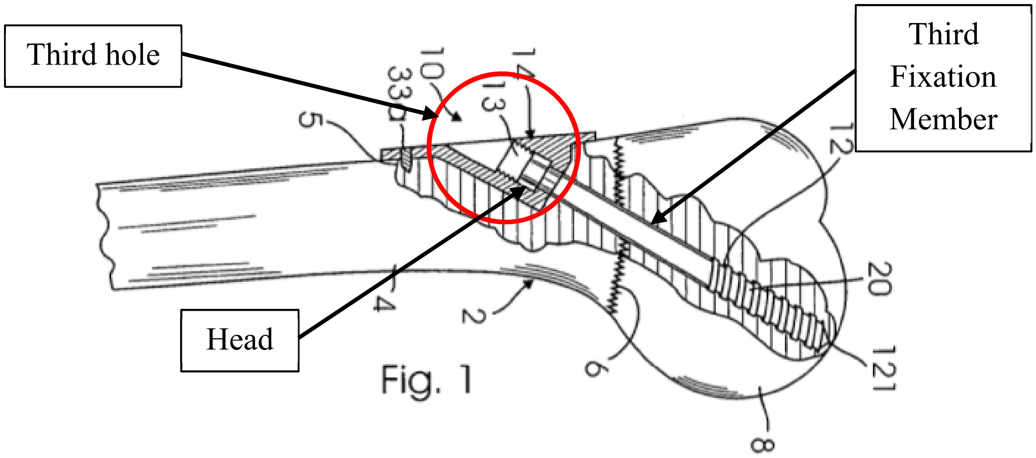
173. A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the

third fixation member, not attached to any portion of the plate, resides in the second bone, as explained above in Section VIII.A.2.v (element [32d]). (*See* Ex. 1004, FIG. 1, 11:18-27).

vi. [32e] and a head of the third fixation member is seated in the third hole,

174. A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member wherein a head of the third fixation member is seated in the third hole, as explained above in Section VIII.A.2.vi (element [32e]). (*See* Ex. 1004, 5:28-31, 6:3-9, FIGS. 5, 7, 13:21-24).

175. Although it is my opinion that Slater discloses this the claim element, I have been asked to consider this element in view of Zahiri. To the extent that Slater is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw. Zahiri discloses a threaded portion 37 in the short barrel portion 38 (third hole), which provides a press fit engagement with the head 22 of the lag screw 12 (third fixation member):



(Ex. 1007, FIG. 1 (annotated); *see also* 7:31-38).

176. Thus, in order to achieve the stated goal from Slater of maintaining the integrity of the third fixation member, it would be obvious to a POSITA to use the seated head of the lag screw from Zahiri to ensure the third fixation member is seated securely in the third hole.

177. Based on these disclosures from Slater and Zahiri, a POSITA would find this element obvious.

vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

178. A POSITA would find that Slater discloses a bone plate configured for inserting a third fixation member through a third hole wherein the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate, as explained above in Section VIII.A.2.vii (element [32f]). (*See* Ex. 1004, FIGS. 5, 1, 7, 13:20-25, 8:25-9:19).

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

179. Slater discloses a bone plate configured for inserting a third fixation member through a third hole wherein the third fixation member is the only fixation member extending across the joint, as explained above in Section VIII.A.2.viii (element [32g]). (*See* Ex. 1004, FIG. 1, 11:18-27).

3. Dependent Claims 33 and 36-39

i. Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

180. A POSITA would find a bone plate configured for inserting a third fixation member through a third hole wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate obvious in view of Slater, as explained above in Section VIII.A.3 (claim 33). (*See* Ex. 1004, FIGS. 9, 2, 11:18-27).

181. Additionally, Zahiri further discloses an incidence angle of a locking screw "A" that is preferably 90°, 150° or 160° from the guide plate but "in the range of from 90° to 170°." (Ex. 1007, 3:59-67). The incidence angle "A" is measured as the obtuse angle between the guide plate and the locking screw trajectory (Ex. 1007, FIG. 4).

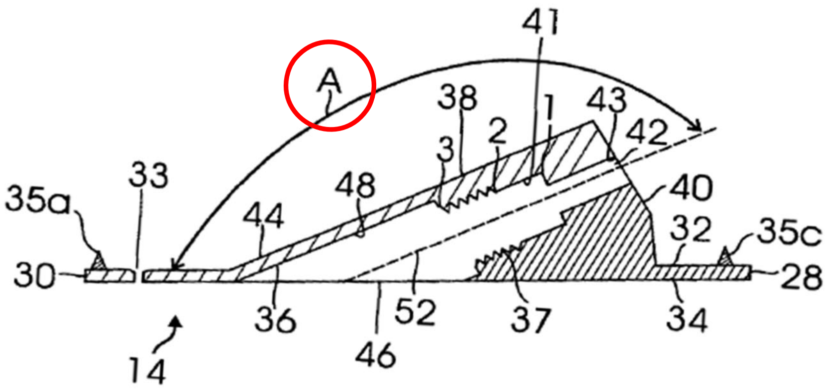


Fig. 4

In contrast, the ’713 Patent refers to angled tab by the angle “α,” which is the acute angle between the plate and the tab in Figure 2:

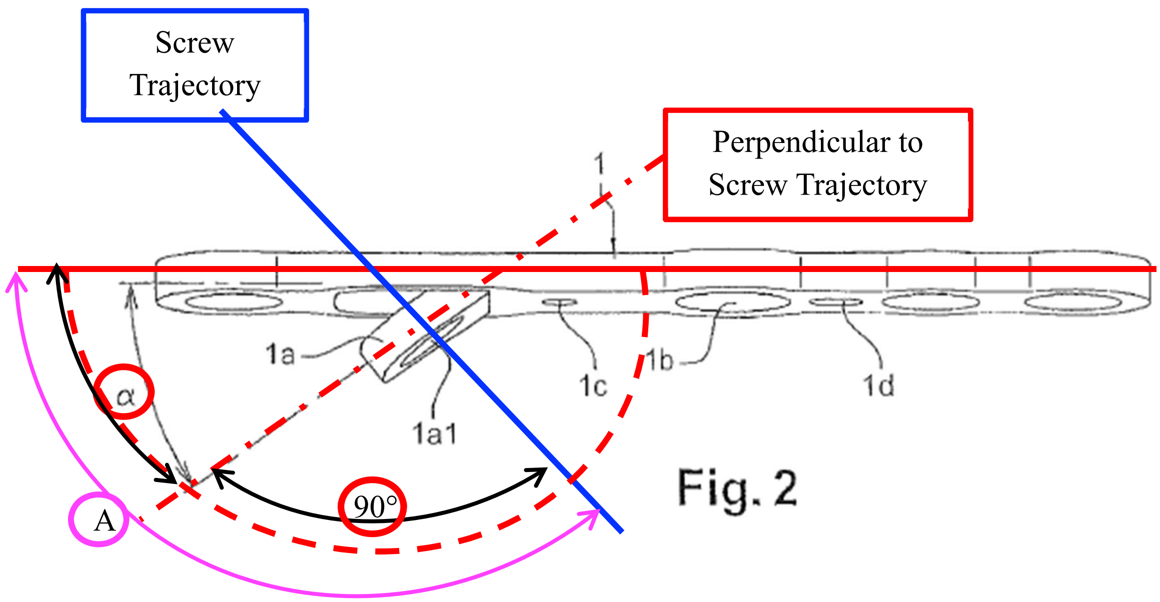
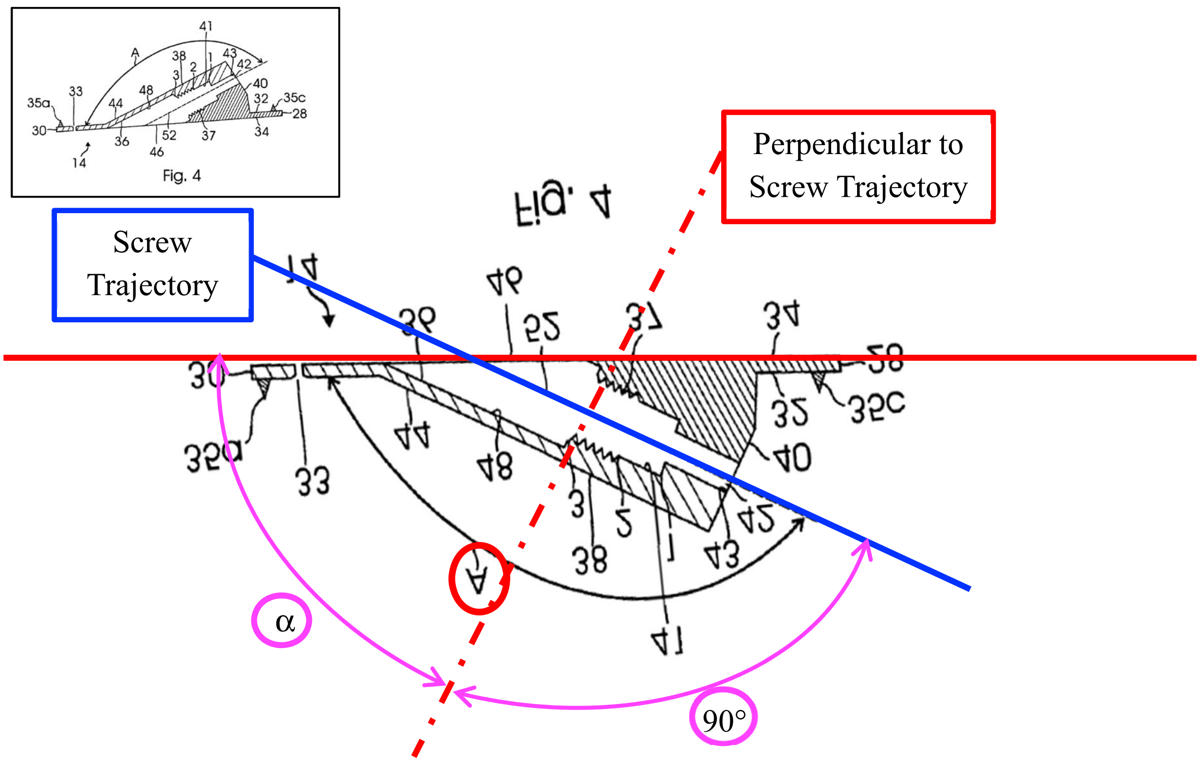


Fig. 2

Zahiri’s Screw Incidence Angle “A” = ’713 Patent α + 90°

(Ex. 1001, FIG. 2 (annotated)).

182. To be comparable to angle "A" in Zahiri, 90° has to be added to "α":



Zahiri's Screw Incidence Angle = "A"
Zahiri's Screw Incidence Angle "A" = '713 Patent α + 90°
Zahiri says that "A" can be 90° - 170°; which equates to α in the '713 Patent equaling 0° - 80°
Zahiri prefers "A" = 150° or 160°, which equates to α in the '713 Patent equaling 60° - 70°

(Ex. 1007, FIG. 4 (annotated)).

183. Therefore, the angle of the hole opening "α," is determined by subtracting 90° from A (hole opening "α," = A - 90°). Accordingly, Zahiri teaches a hole-opening angle "α," at 0° to 80° with respect to the longitudinal surface of the guide plate.

184. Both Slater and Zahiri teach a third hole configured at an angle with respect to the longitudinal axis of the plate and that angle encompasses the claimed

range (i.e., Zahiri's range of 0° to 80° encompasses the claimed range of 30° to 60°). Thus, it would also be obvious to a POSITA that a fixation member configured to diagonally secure a joint would be angled between 30° and 60° with respect to the longitudinal axis of the plate.

185. Based on these disclosures from Slater and Zahiri, a POSITA would find this claim obvious.

ii. Claim 38: The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

186. Zahiri discloses additional pins that "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). Figure 8 shows the location of these pin holes:

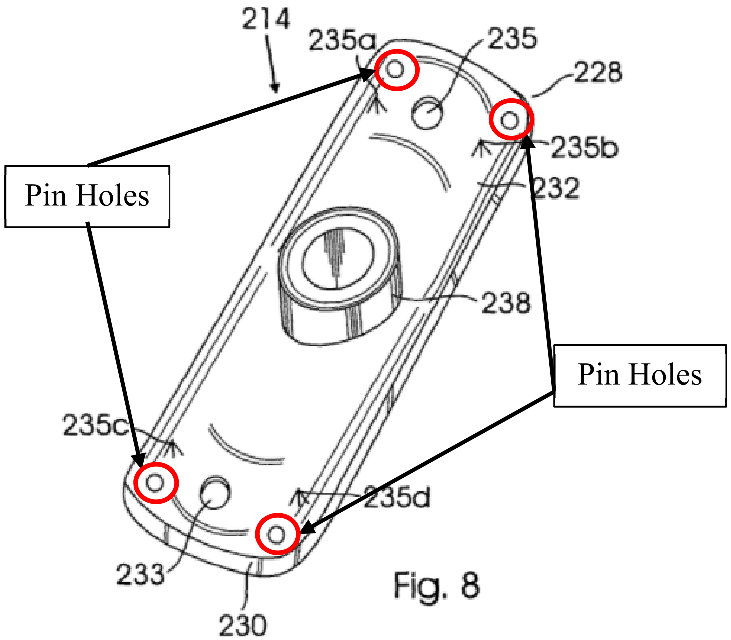


Fig. 8

(Ex. 1007, FIG. 8 (annotated)). Additionally, after "the lag screw 12 is settled inside of the epiphysis 8 the four pins are pulled out, and a medium size screw 33a is pressed and turned through the hole [2]33 of the plate [2]14 and into the bone diaphyseal segment." (Ex. 1007, 7:63-8:11).

187. Since Slater describes a goal of reducing the risk of complications and improving the likelihood of painless, normal walking by the patient, a POSITA would be motivated to utilize the pin holes in Zahiri to ensure proper placement and alignment of the plate during implantation. Use of temporary fixation pins was common at the time of invention, and would have been readily utilized by a POSITA given the explicit disclosure in Zahiri and the desire to improve the placement and alignment Slater's plate.

188. Based on these disclosures from Slater and Zahiri, a POSITA would find this claim obvious.

D. Ground 4: Obviousness over Arnould in view of Zahiri

189. Independent claim 32, and dependent claims 33 and 36-39, are obvious in view of the combination of Arnould and Zahiri. Below I explain how each element of claims 32, 33 and 36-39 are disclosed, taught, and/or suggested by the combination of Arnould and Zahiri.

1. Basis for the Combination of Arnould and Zahiri

190. The scope and content of the prior art includes Arnould and Zahiri, which collectively disclose all of the elements of claims 32-33 and 36-39. There are no differences between the subject matter of these claims and the combination of Arnould and Zahiri.

191. Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone or across a fracture. (Ex. 1006, ¶6; Ex. 1007, 2:20-31). A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. Arnould and Zahiri are therefore in analogous fields of invention. Arnould's bone plate comprises a hole 25 that determines the relative position of a screw 30 that passes through and fuses the joint between the metatarsal and phalanx. (Ex. 1006, ¶31). Arnould

explains that "the screw works mainly in traction" and that "[w]ith a single action consisting of screwing in this long screw, the surgeon automatically brings the two bones to be fused closer to each other." (Ex. 1006, ¶6).

192. A POSITA knows that screws positioned across an interface, "working in traction" are providing compression at the interface. Arnould further discloses a variable fixation angle between the longitudinal axis of the plate body, selected by the surgeon to fuse the metatarsal and phalanx. (Ex. 1006, ¶¶27, 32). In other words, the surgeon "has the possibility of modifying the angle α," indicating the surgeon can choose the angle at which the fixation member is inserted to achieve an optimal interface between the screw and the bone. (Ex. 1006, ¶38).

193. While a POSITA may find that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate, Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri, and position the third hole at an angle relative to the longitudinal thickness of the bone plate. Zahiri discloses a bone plate configured to fuse a first and second bone part with an angle fixation member and compress the bone fracture:

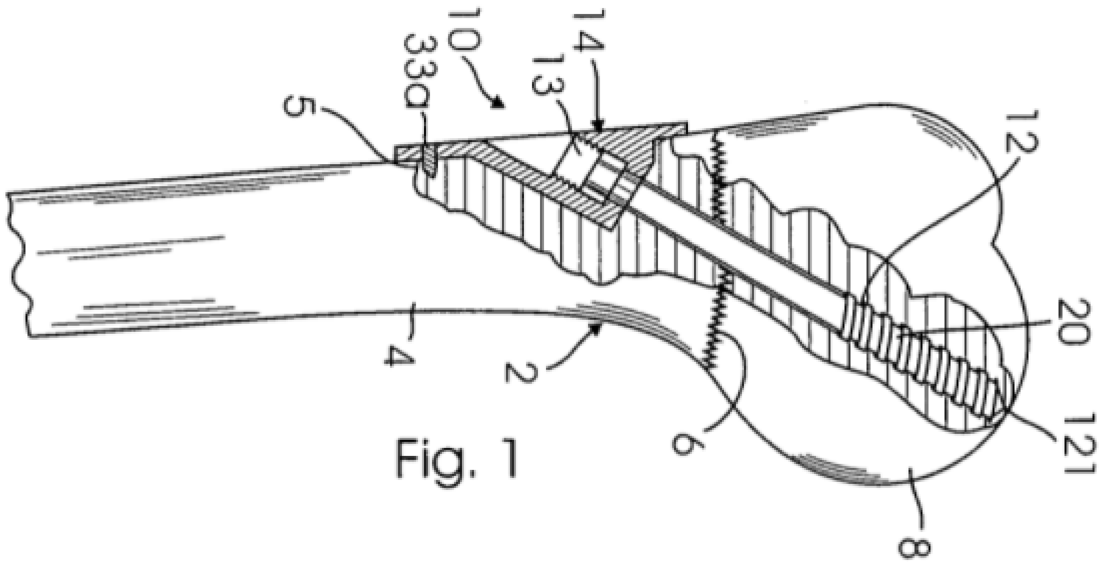
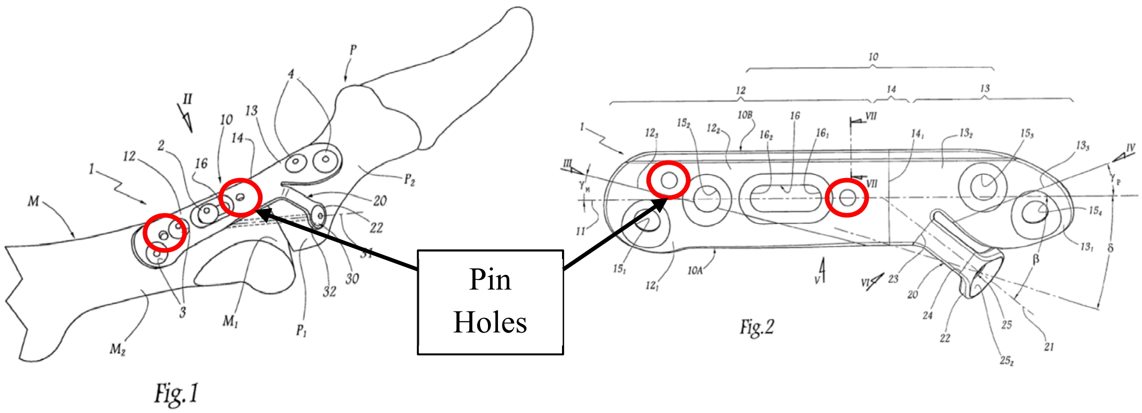


Fig. 1

(Ex. 1007, FIG. 1; 2:45-48). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11). A POSITA would understand that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate.

194. While Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted, the figures show pin

holes that are intended to be used to temporarily secure the plate with k-wires during the implantation process:



(Ex. 1006, FIGS. 1, 2 (annotated)). K-wires are commonly used for temporary placement, alignment and immobilization of bone plates so that the surgeon can correctly position and align a plate. Arnould discusses the difficultly of proper plate alignment faced by the surgeon during implantation and the importance that proper placement has on patients' comfort. (Ex. 1006, ¶3). Zahiri further discusses the importance of plate alignment and specifically discloses the use of temporary locking pins to temporarily secure the bone plate to the bone during implantation. (Ex. 1007, 3:10-18). As this would be done before the plate is permanently affixed, a POSITA would look to incorporate the use of temporary pins disclosed by Zahiri into Arnould to ensure correct placement. (*See* Ex. 1006, ¶¶3, 31).

195. Similarly, Zahiri discloses four small holes in the corner of the bone plate that are used with pins to temporarily hold the bone plate in place during implantation:

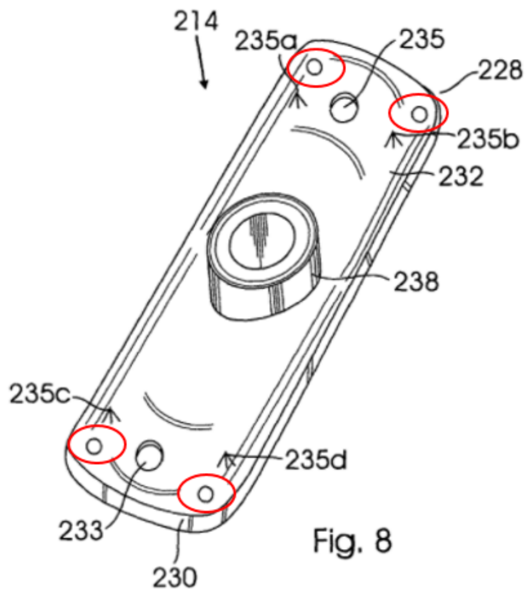


Fig. 8

(Ex. 1007, FIG. 8 (annotated); *see also* 3:10-18 ("[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.")). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (Ex. 1007, 3:10-18). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (Ex. 1007, 3:10-18).

196. Thus, a POSITA would understand that the temporary pin holes, as disclosed in Zahiri, could be implemented into Arnould's bone plate to temporarily maintain plate alignment during implantation. A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins and would render the incorporation of Zahiri's guide holes obvious. (Ex. 1006, FIG. 1). Zahiri discloses a known technique for improving plate alignment during implantation.

197. Thus, a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement.

2. Independent Claim 32

i. [32Pre] A method of fusing a joint, the method comprising:

198. As shown in Figure 1 below, Arnould discloses a bone plate configured for arthrodesis of a joint between the first metatarsal and the first phalanx:

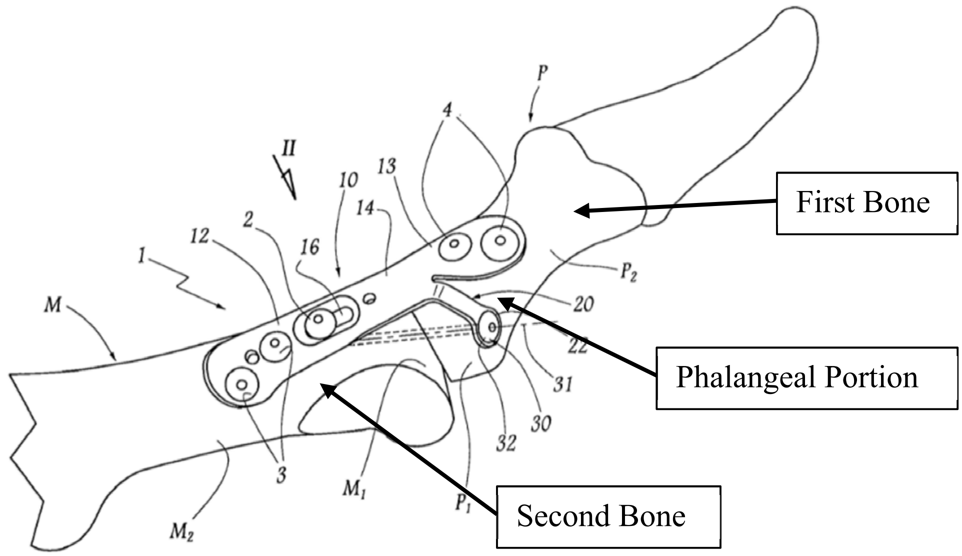


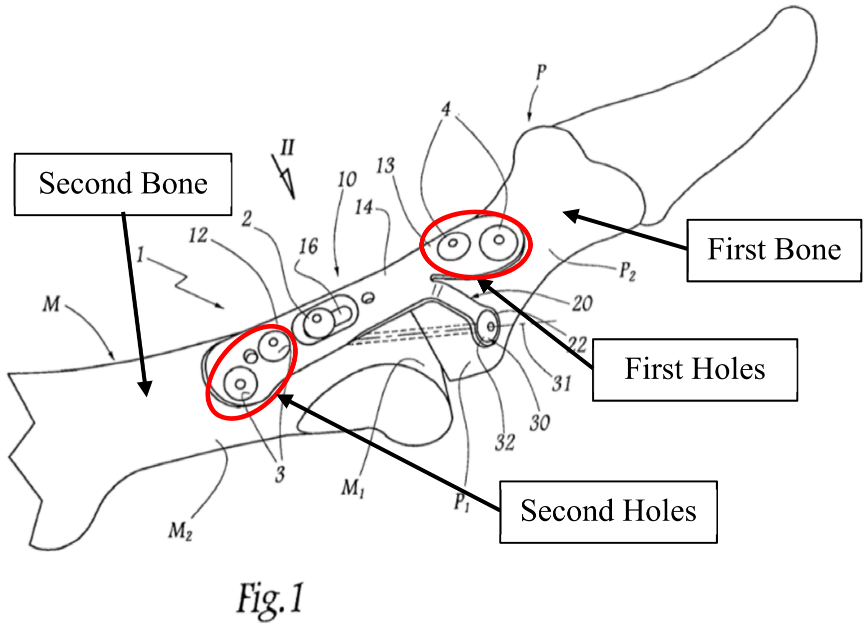
Fig.1

199. Arnould specifically states that "Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." (Ex. 1006, ¶11).

200. Based on Figure 1 and the cited portions of Arnould, Arnould clearly discloses a plate that is used to perform the claimed method of joint fusion.

ii. [32a] spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

201. Arnould's bone plate comprises four screw holes 15_1-15_4 configured to anchor the plate body to the phalanx (first bone) through holes 15_3-15_4 (first holes), and to the metatarsal (second bone) through holes 15_1-15_2 (second holes):



(Ex. 1006, FIG. 1 (annotated) *see also* FIG. 2).

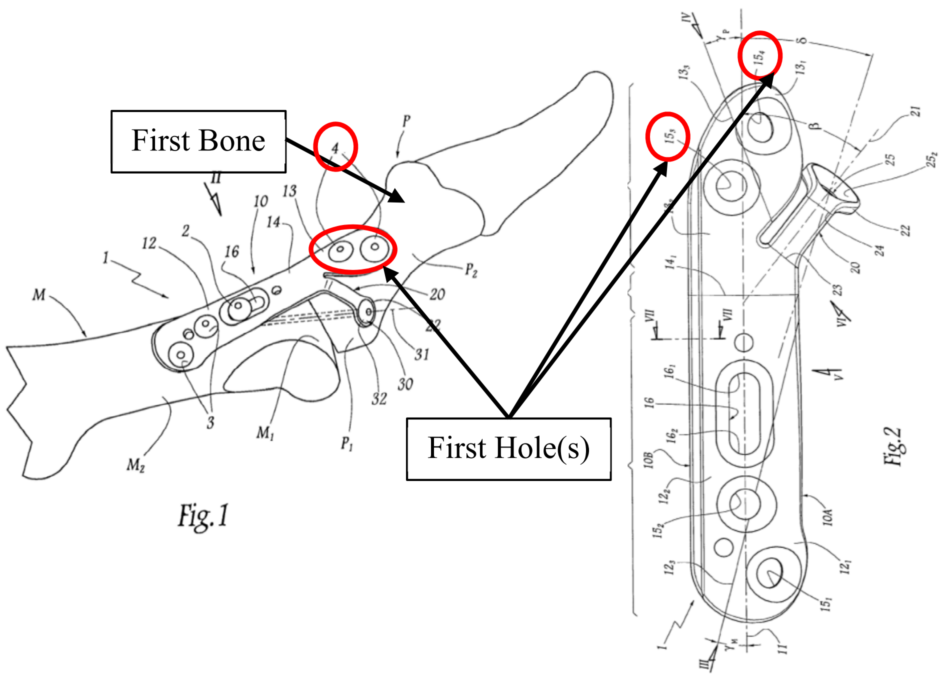
202. Arnould also states, "[t]he screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2," and that "[b]efore or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P." (Ex. 1006, ¶¶33-34).

203. Based on Figure 1 and the cited portions of Arnould, Arnould clearly discloses a plate spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone

of the joint and a second hole of the bone plate is aligned with a second bone of the joint.

iii. [32b] inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

204. Arnould discloses the steps of inserting screws 4 into holes 15_3 and 15_4, and attaching to the phalanx (first bone):



(Ex. 1006, FIGS. 1, 2 (annotated)).

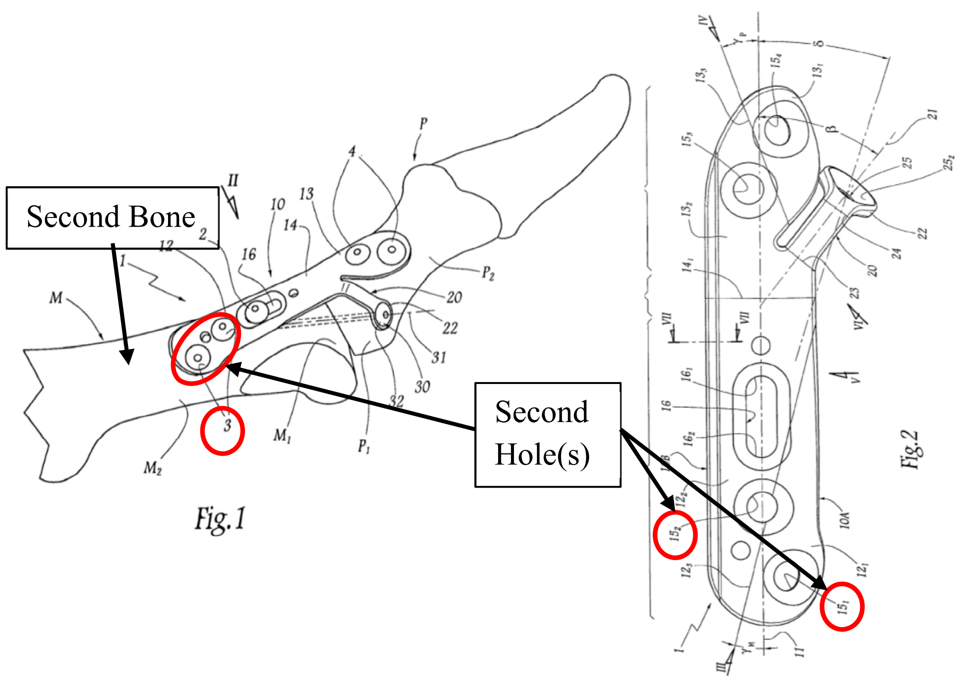
205. Arnould also states, "[i]n order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner." (Ex. 1006, ¶21).

206. Paragraph 34 describes the through-holes and bone-anchoring screws in more detail: "[b]efore or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P." (Ex. 1006, ¶34).

207. Based on Figures 1 and 2 and the cited portions of Arnould, Arnould clearly discloses inserting a first fixation member through the first hole of the plate and into the first bone of the joint.

iv. [32c] inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

208. Arnould discloses the steps of inserting screws 3 into holes 15_1 and 15_2, and attaching to the metatarsal (second bone):



(Ex. 1006, FIGS. 1, 2 (annotated)).

209. Arnould also states, "[i]n order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner." (Ex. 1006, ¶21).

210. Paragraph 33 describes the through-holes and bone-anchoring screws in more detail: "[t]he screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2." (Ex. 1006, ¶33).

211. Based on Figures 1 and 2 and the cited portions of Arnould, Arnould clearly discloses inserting a second fixation member through the second hole of the plate and into the second bone of the joint.

v. [32d] inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone

212. Figure 1 of Arnould shows how screw 30 is configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

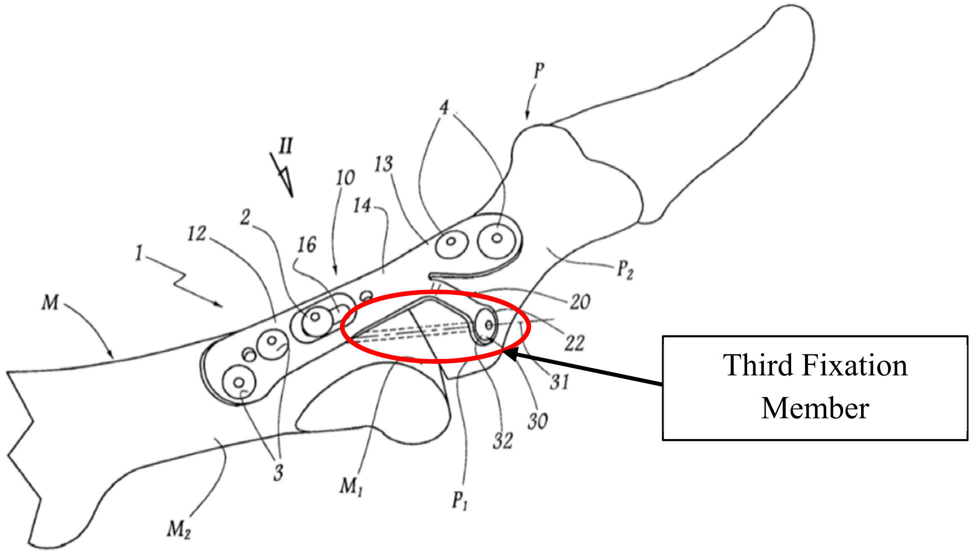


Fig. 1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶¶6, 32). Arnould states, "[t]he screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above." (Ex. 1006, ¶32). Based on these disclosures from Arnould, a POSITA would understand that the free end of screw 30 resides in the second bone and does not attach to any portion of the bone plate.

213. Based on Figure 1 and the cited portions of Arnould, a POSITA would understand that Arnould discloses inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the

second bone so that a free end of the third fixation member, not attached to any portion of the plate, resides in the second bone.

vi. [32e] and a head of the third fixation member is seated in the third hole,

214. Arnould's bone plate comprises screw 30 configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone). (Ex. 1006, ¶32). Screw 30 is tightened until the head 32 is abutted against the edge of hole 25. (Ex. 1006, ¶32). In order for screw 30 to lock in place, hole 25 comprises a concave surface that is substantially complementary with head 32 of screw 30. (Ex. 1006, ¶27).

215. Based on the cited portions of Arnould, a POSITA would understand that Arnould discloses a head of the third fixation member is seated in the third hole.

216. Although it is my opinion that Arnould discloses this the claim element, I have been asked to consider this element in view of Zahiri. To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the placement of the angled fixation screw. Zahiri discloses a threaded portion 37 in the short barrel portion 38 (third hole), which provides a press fit engagement with the head 22 of the lag screw 12 (third fixation member):

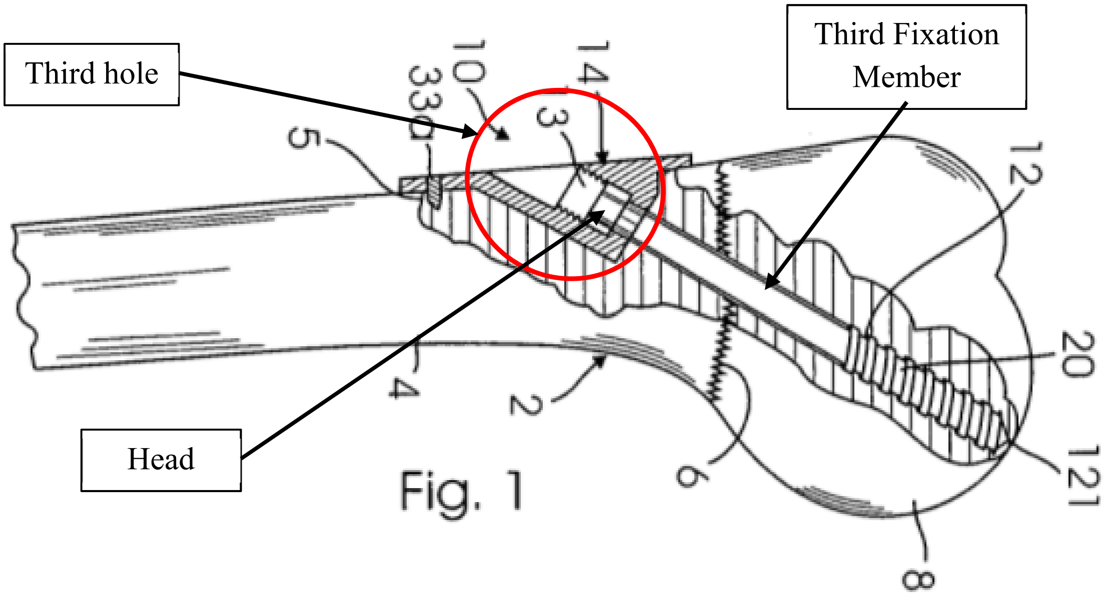


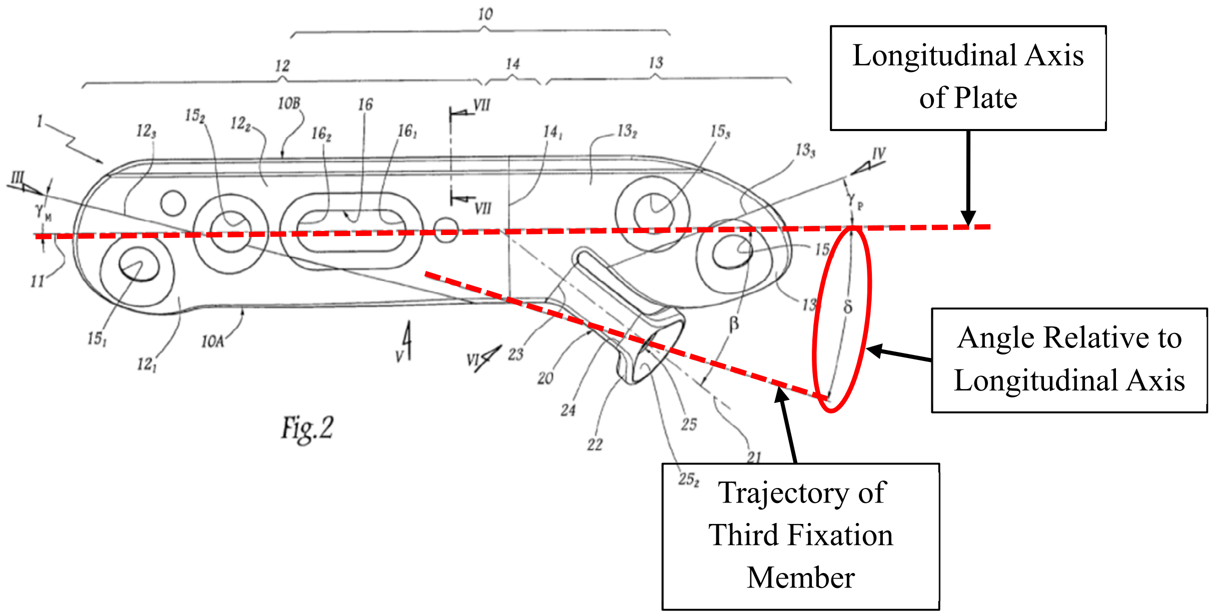
Fig. 1

(Ex. 1007, FIG. 1 (annotated); *see also* 7:31-38). Thus, in order to achieve the stated goal from Arnould of locking screw 30 by the head 32, it would be obvious to a POSITA to use the seated head of the lag screw from Zahiri to ensure the third fixation member is seated in the third hole.

217. Based on the cited portions of Arnould and Zahiri, a POSITA would understand that Arnould in view of Zahiri discloses a head of the third fixation member is seated in the third hole.

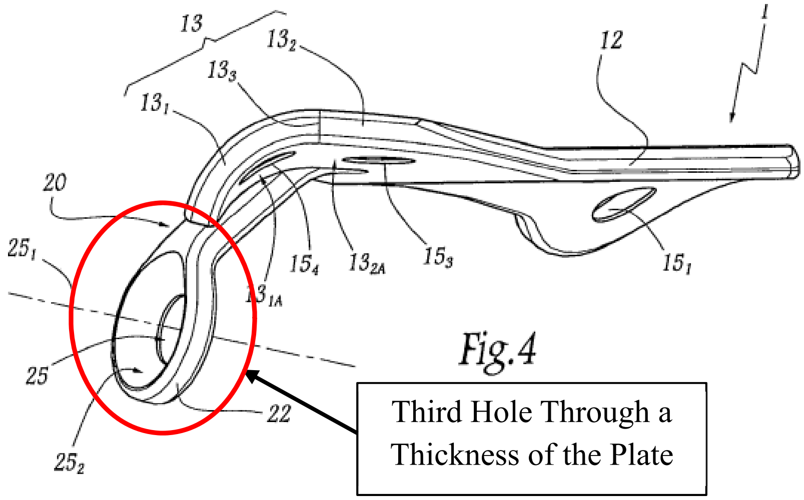
vii. [32f] the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate,

218. Arnould describes a screw hole 25 (third hole) configured such that the screw 30 forms a non-zero angle in relation to the longitudinal direction of the plate body:



(Ex. 1006, FIG. 2 (annotated)). More specifically, the trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate (δ). As Arnould states, "[t]he hole 25 is provided to receive the screw 30 so that, depending on the direction of observation corresponding to arrow II, the longitudinal axis 31 of this screw can be inclined in relation to the longitudinal direction 11 of the plate body 10, forming a non-zero angle δ with this direction 11." (Ex. 1006, FIG. 2, ¶27).

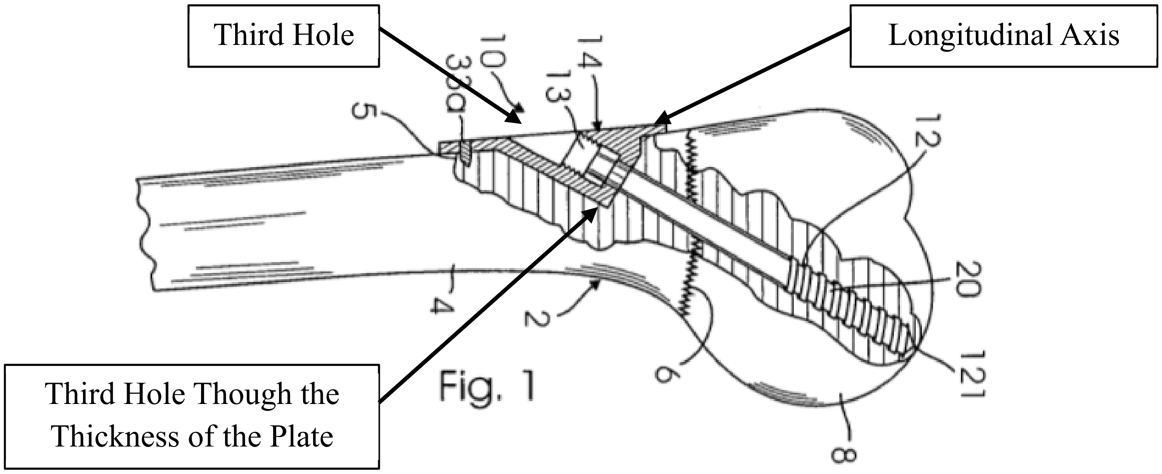
219. Figure 4 of Arnould shows how there is a thickness to the plate where screw 30 is inserted into hole 25:



(Ex. 1006, FIG. 4 (annotated)).

220. Based on Figures 2 and 4 and the cited portions of Arnould, a POSITA would understand that Arnould discloses the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate.

221. Although it is my opinion that Arnould discloses this the claim element, I have been asked to consider this element in view of Zahiri. To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw, which includes putting the screw through a thickness of the plate:



(Ex. 1007, FIG. 1 (annotated), *see also* 7:63-8:11).

222. Based on the cited portions of Arnould and Zahiri, a POSITA would understand that Arnould in view of Zahiri discloses the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate.

viii. [32g] wherein the third fixation member is the only fixation member extending across the joint.

223. Arnould depicts a bone plate comprising one hole 25 configured to receive an angled screw 30 that passes through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

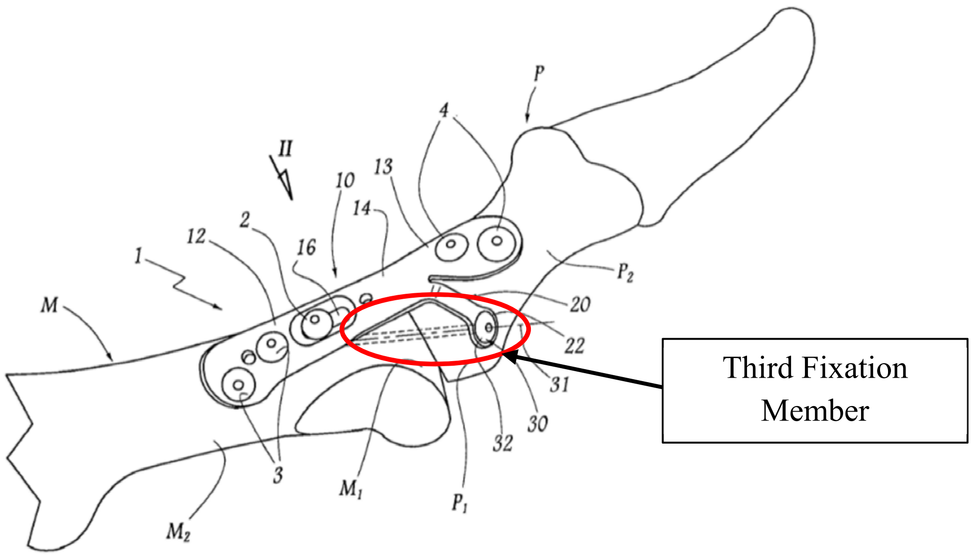


Fig. 1

(Ex. 1006, FIG. 1 (annotated)). Arnould also states, "[t]he screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above." (Ex. 1006, ¶32).

224. Additionally, Zahiri depicts a bone plate comprising a guide hole through a barrel portion configured to angle a lag screw through a first bone and into a second bone. (Ex. 1007, 2:23-36). Figure 1 of Zahiri shows that the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone fragment and the second bone fragment:

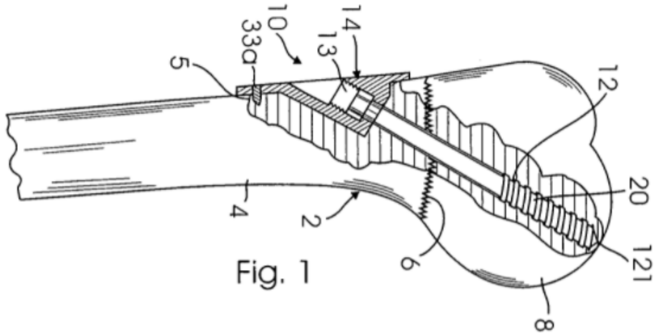


Fig. 1

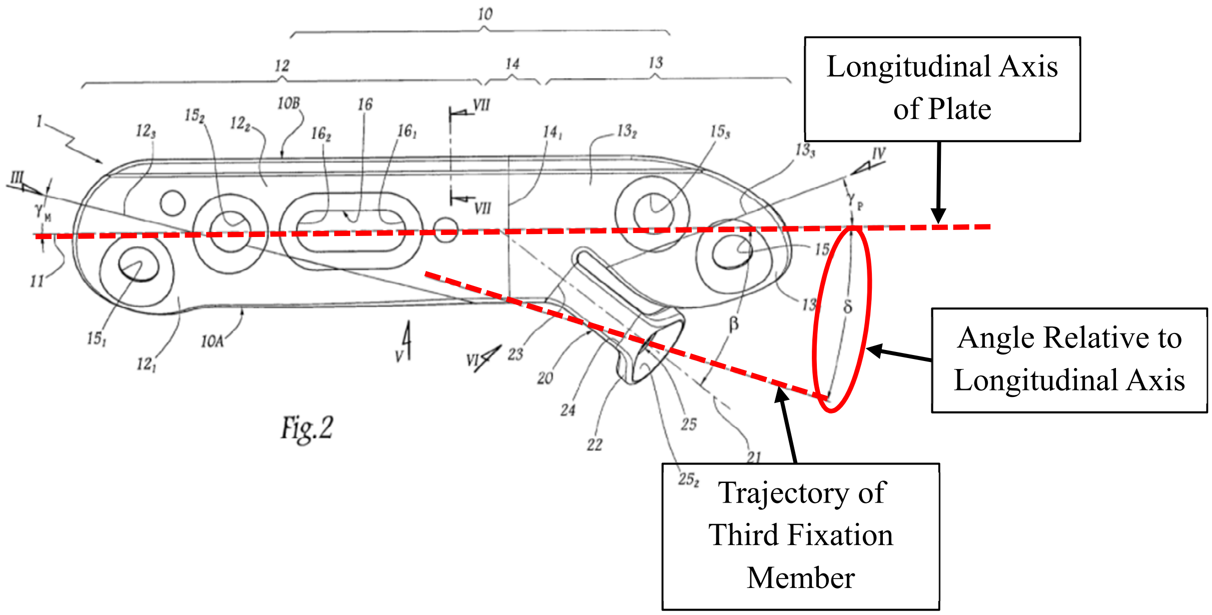
(Ex. 1007, FIG. 1; *see also* 2:23-36). Therefore, a POSITA would understand that both Arnould's bone plate and Zahiri's bone plate are configured for only one compression screw to intersect the joint and/or fracture line.

225. Based on the cited portions of Arnould and Zahiri, a POSITA would understand that Arnould in view of Zahiri discloses that the third fixation member is the only fixation member extending across the joint.

3. Dependent Claims 33, 36-39

i. Claim 33: The method of claim 32, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

226. Arnould discloses the trajectory of screw 30, and therefore hole 25, forms a non-zero angle relative to the plate body in the longitudinal direction at angle δ, where angle δ is less than 45°:



(Ex. 1006, FIG. 2 (annotated); *see also* ¶27). Arnould specifically describes how "[f]or anatomical reasons, the angle δ is advantageously chosen to be less than 45." (Ex. 1006, ¶27). Additionally, hole 25 is further connected to leg 20, where leg 20 is offset at angle β with respect to the longitudinal axis of the plate. (Ex. 1006, ¶25). Thus, a POSITA would understand that the disclosed angle range of Arnould would sometimes fall within the clamed angle range.

227. Although it is my opinion that Arnould discloses this the claim element, I have been asked to consider this element in view of Zahiri. To the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw. A POSITA looking to use Arnould's plate in an application that does not allow for the leg 20 to wrap around the bone would also look to

other prior art plates, such as Zahiri, that could be used in such an application.

228. A POSITA would understand that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate.

229. Zahiri further discloses an incidence angle of a locking screw "A" that is preferably 90°, 150° or 160° from the guide plate but "in the range of from 90° to 170°." (Ex. 1007, 3:59-67). The incidence angle "A" is measured as the obtuse angle between the guide plate and the locking screw trajectory. (Ex. 1007, FIG. 4).

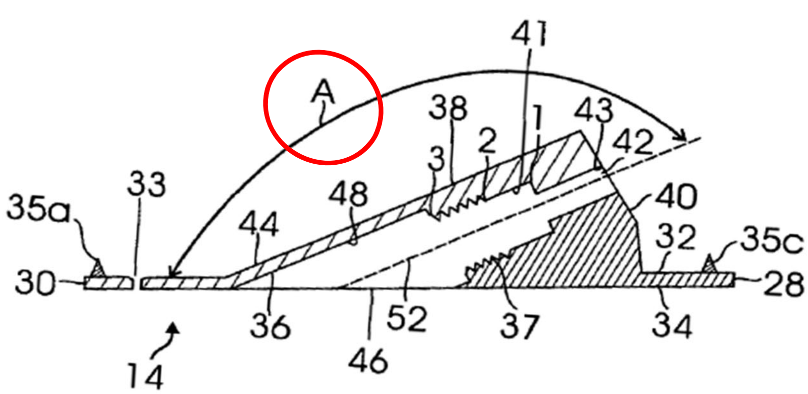
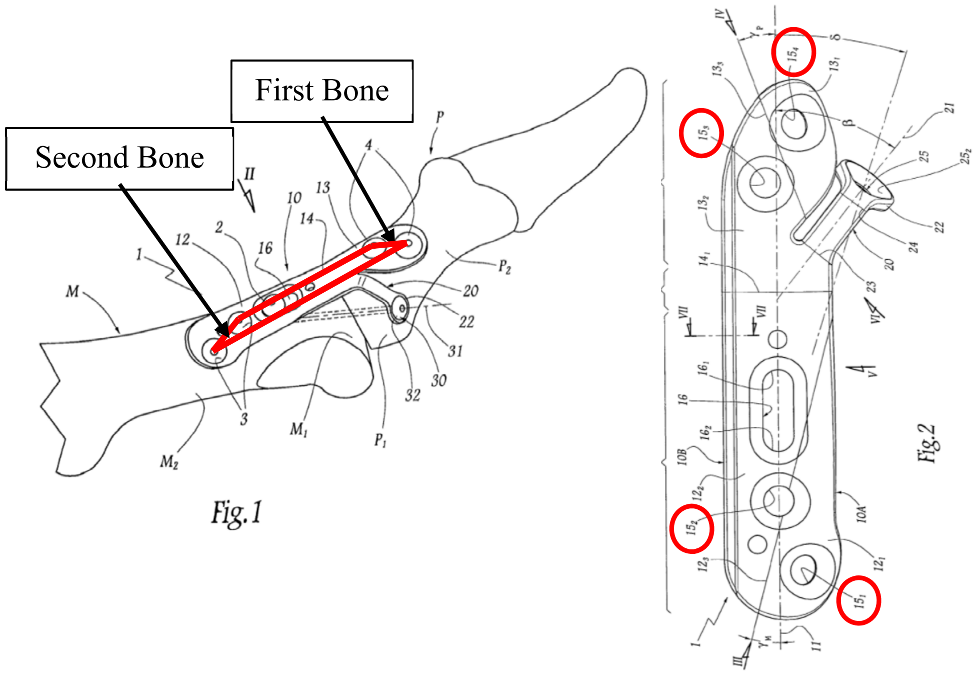


Fig. 4



(Ex. 1006, FIGS. 1, 2 (annotated); *see also* ¶21). Holes 15_1 and 15_2 are configured to receive screws 3 and attach to the metatarsal (second bone), and holes 15_3 and 15_4 are configured to receive screws 4 and attach to the phalanx (first bone). (Ex. 1006, FIGS. 1, 2; *see also* ¶21).

233. Additionally, Zahiri's bone plate comprises four holes 31a-d in a rectangular (i.e., quadrilateral) orientation, where the holes are intended for anchoring the plate to the bone:

v. Claim 38: The method of claim 37, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

240. Arnould discloses partially affixing the bone plate so that surgeon can correctly place the plate before the plate is permanently affixed. (Ex. 1006, ¶31). While Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted, the figures show pin holes that are used to temporarily secure the plate with k-wires during the implantation process:

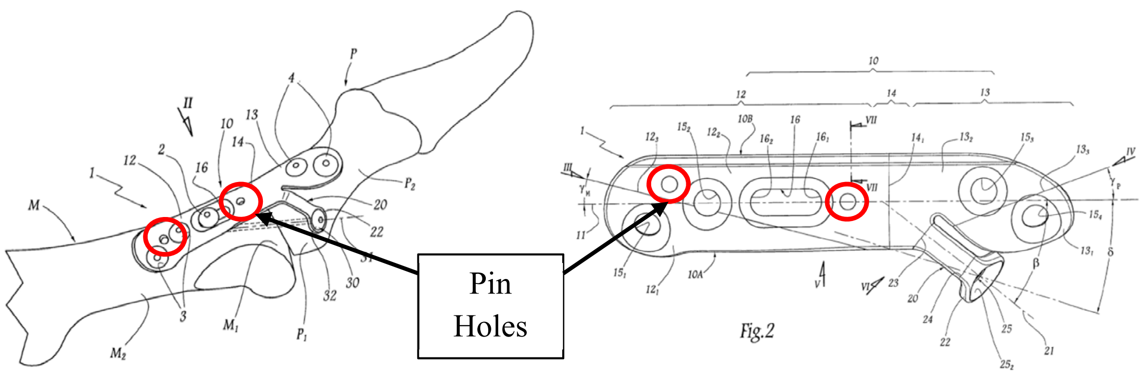


Fig.1

(Ex. 1006, FIGS. 1, 2 (annotated)). K-wires are commonly used for temporary placement and immobilization of bone plates so that the surgeon can correctly position and align a plate.

241. Thus, a POSITA would find this claim obvious in view of Arnould.

242. Although it is my opinion that Arnould discloses this the claim element, I have been asked to consider this element in view of Zahiri. To the extent that Arnould does not render this element obvious, a POSITA would have

readily looked to Zahiri. Zahiri explicitly discloses additional pins that "are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18). Figure 8 shows the location of these pin holes:

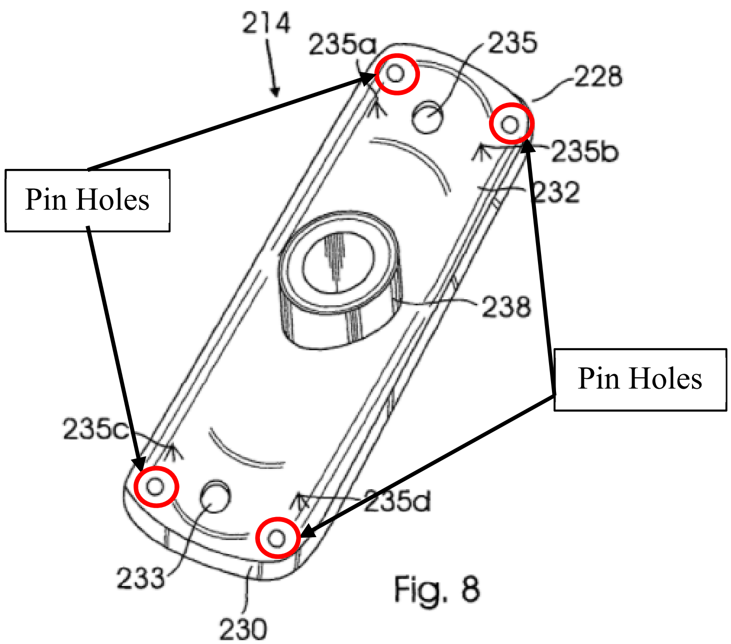


Fig. 8

(Ex. 1007, FIG. 8 (annotated)). Additionally, after "the lag screw 12 is settled inside of the epiphysis 8 the four pins are pulled out, and a medium size screw 33a is pressed and turned through the hole [2]33 of the plate [2]14 and into the bone diaphyseal segment." (Ex. 1007, 7:63-8:11). Since Arnould describes temporarily securing the plate, a POSITA would be motivated to utilize the pin holes in Zahiri to ensure proper placement and

alignment of the plate during implantation. Use of temporary fixation pins was common at the time of invention, and would have been readily utilized by a POSITA given the explicit disclosure in Zahiri and the desire to temporarily secure Arnold's plate.

243. Thus, a POSITA would find this claim obvious in view of Arnould and Zahiri.

vi. Claim 39: The method of claim 32, wherein the joint is one of the anatomical joints of the human body in the foot or hand.

244. Arnould discloses a bone plate for arthrodesis of the metatarsophalangeal joint which is a joint within the foot:

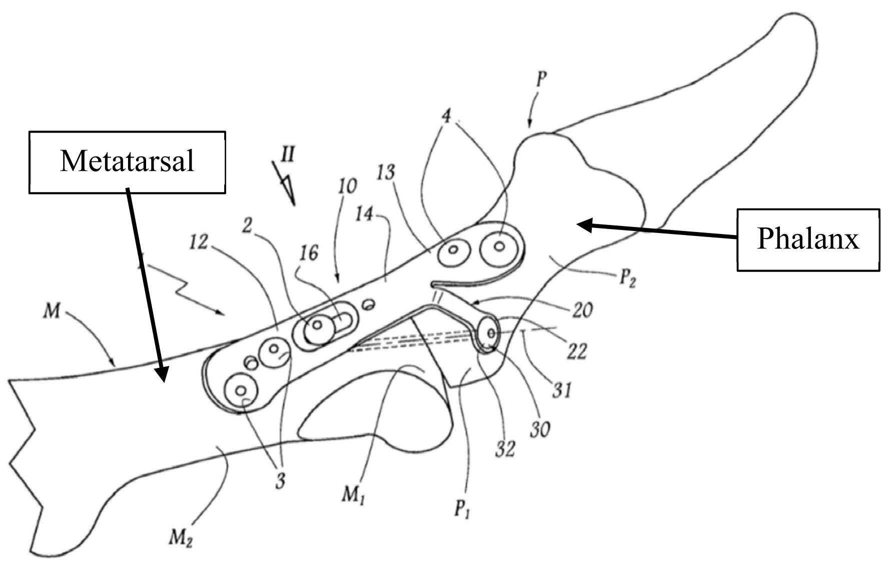


Fig. 1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶5). Arnould specifically states that "Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." (Ex. 1006, ¶11). A POSITA would understand that the metatarsal and phalanx are bones in the foot.

245. Thus, a POSITA would find that this claim is taught by Arnould.

E. Ground 5: Obviousness over Arnould in view of Zahiri and further in view of Myerson

246. Dependent claims 34 and 35 are obvious in view of the combination of Arnould, Zahiri, and Myerson. Below I explain how each element of claims 34 and 35 are disclosed, taught, and/or suggested by the combination of Arnould, Zahiri, and Myerson.

1. Basis for Combination of Arnould, Zahiri, and Myerson

247. A POSITA would be motivated to combine Arnould and Zahiri for at least the reasons set forth in Section IX.D.1. Additionally, Arnould describes the desire to completely secure the plate to the bone using the screws. (Ex. 1006, ¶¶33-34). In analogous art, Myerson discloses a bone plate for fusion of the MTP joint as well as for receiving a locking screw in combination with threaded holes to lock the fixation screws in place. (Ex. 1008, ¶22).

248. Thus, the use of locking screws or threaded holes to prevent the screws from backing out is a well-known element of prior art to obtain a predictable

result. Therefore, incorporating locking screws or threaded holes into Arnould's bone plate can be accomplished through a simple substitution to provide a known advantage and accomplish a predictable result. A POSITA would be motivated to apply the teachings of Myerson and modify Arnould's bone plate.

2. Independent Claim 32

249. Independent claim 32, from which claims 34, and 35 depend, is obvious in view of Arnould and Zahiri (Ground 4). *See* Section IX.D.2.

3. Dependent Claims 34 and 35

i. Claim 34: The method of claim 32, wherein the first and second holes are locking holes.

250. As shown in the annotated Figure 2 below, Myerson's bone plate comprises screw holes 22 (first hole) and 32, 36 (second hole) configured to receive locking screws with the plate having locking threads within the screw holes:

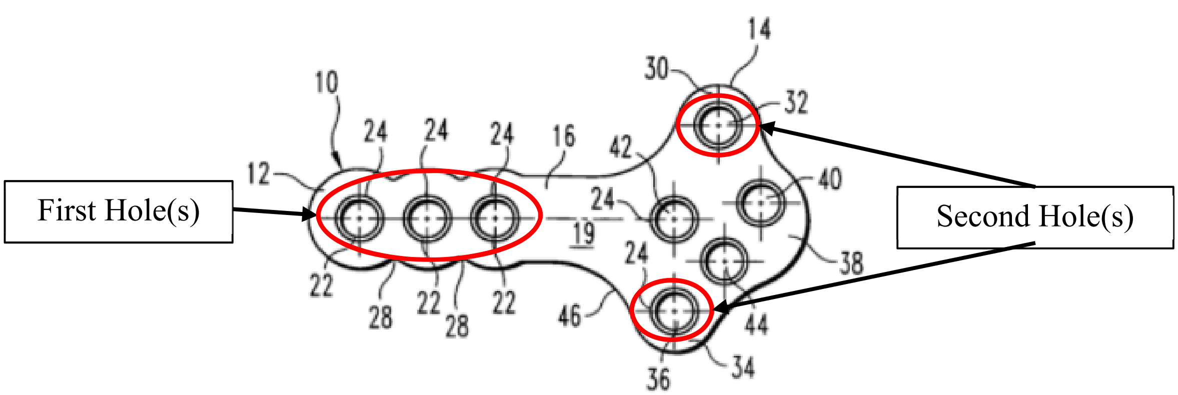


Fig. 2

(Ex. 1008, FIG. 2 (annotated)). Myerson specifically describes that "the screw holes are designed to receive locking screws, such as by the incorporation of locking threads (not shown) within the screw hole." (Ex. 1008, ¶22; *see also* ¶25). In addition Myerson provides explicit description of the locking thread: "In a specific embodiment, the locking screws may be at 0.5 mm pitch, with a 4.0 mm major diameter and a 3.6mm minor diameter." (Ex. 1008, ¶22),

251. The use of locking screws with locking threaded holes, as described in Myerson, with Arnould's plate, provides a solution and a predictable result in the field of bone plates, to the known problem of screws loosening and backing out over time, something explicitly recognized by Slater. (Ex. 1004, 2:9-14). Myerson identifies a known method for securing screws and preventing screws from backing out: use of locking screws with locking threaded holes. (Ex. 1008, ¶22).

252. Thus, a POSITA would have been motivated to combine this teaching from Myerson with Arnould's plate, as modified by Zahiri as discussed with respect to claim 32, because the use of locking screws with locking threaded holes are a known technique to prevent the screws from backing out.

253. Based on the cited portions of Myerson and Arnould, a POSITA would understand that Arnould's plate, as modified by Zahiri as discussed with

respect to claim 32, could incorporate locking holes into the first and second holes, thus making claim 34 obvious.

ii. Claim 35: The method of claim 34, wherein the first and second holes are threaded.

254. For the same reasons given with respect to claim 34 and explained above, a POSITA would understand that Arnould's plate, as modified by Zahiri as discussed with respect to claim 32, could incorporate locking threaded holes into the first and second holes, thus making claim 35 obvious.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)		
	Application Number	
	Filing Date	
	First Named Inventor	Bernard Prandi
	Art Unit	3775
	Examiner Name	C. J. Beccia
	Attorney Docket Number	TRAUMA 3.3-647 CON

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Examiner Name	C. J. Beccia
	Attorney Docket Number	TRAUMA 3.3-647 CON

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	11	7819903		2010-10-26	Fraser et al.	
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	15	7695472		2010-04-13	Young	
	16	7491220		2009-02-17	Coughln	
	17	7344538		2008-03-18	Myerson et al.	
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	19	7326218		2008-02-05	Sterett et al.	

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	Art Unit	3775
	Examiner Name	C. J. Beccia
	Attorney Docket Number	TRAUMA 3.3-647 CON

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	50	20070270850		2007-03-13	Huebner	
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	Attorney Docket Number	TRAUMA 3.3-647 CON

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	4	2002098306	WO	A1	2002-12-12	Australian Surgical Design And et al.		☐
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	7	2764183	FR	A1	1998-12-11	Afriat Jacques	English translation of Abstract only.	☒
	8	2846870	FR	A1	2004-05-14	Fixano	English language translation of Abstract only	☒
	9	2912895	FR	A1	2008-08-29	Small Bone Innovations Interna	English translation of Abstract only.	☒
	10	3027148	DE	A1	1981-12-03	Straumann Inst Ag	English equivalent is US 4,388,921	☒
	11	3630862	DE	A1	1988-03-17	Mecron Med Prod Gmbh	English language translation of Abstract only	☒
	12	590290	FR	B	1925-03-13	Lauwens	English translation of the claims only.	☒
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	11	7819903		2010-10-26	Fraser et al.	
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	13	7771457		2010-08-10	Kay et al.	
	14	7766948		2010-08-03	Leung	
	15	7695472		2010-04-13	Young	
	16	7491220		2009-02-17	Coughln	
	17	7344538		2008-03-18	Myerson et al.	
	18	7341589		2008-03-11	Weaver et al.	
	19	7326218		2008-02-05	Sterett et al.	

Docket No.: TRAUMA 3.3-647 CON
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Prandi et al.

Application No.: 14/041,706 Confirmation No.: 3912

Filed: September 30, 2013 Art Unit: 3775

For: ORTHOPEDIC IMPLANT IN THE FORM OF A PLATE TO BE FIXED BETWEEN TWO BONE PARTS Examiner: C. J. Beccia

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Dear Madam:

Prior to initiation of the prosecution of the above-identified pending U.S. patent application, the following amendments and remarks are respectfully submitted.

IN THE CLAIMS

1. (canceled).

2. (new) A method of fusing a joint, the method comprising:

spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

inserting a third fixation member into an aperture formed in the plate, through a third hole recessed at least partially below a bottom surface of the plate and the aperture, into the first bone, across the joint, and into the second bone.

3. (new) The method of claim 2, wherein the third hole is located on an angled member extending downward at an angle with respect to the bottom surface of the plate.

4. (new) The method of claim 3, wherein the aperture is a guide slot in the plate arranged above the third hole, and insertion of the third fixation member through the third hole includes inserting the third fixation member through the guide slot and on a trajectory which extends through the third hole.

5. (new) The method claim 4, wherein the angled member is angled by about between 30° and 60° with respect to a longitudinal axis of the plate.

6. (new) The method of claim 3, further comprising forming a cavity in the first bone with a tool, and positioning the angled member at least partially within the cavity.

7. (new) The method of claim 3, wherein the angled member extends from the bottom surface of the bone plate.

8. (new) The method of claim 2, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

9. (new) The method of claim 8, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

10. (new) The method of claim 2, wherein the first and second holes are locking holes.

11. (new) The method of claim 10, wherein the first and second holes include threading for engaging with the first and second fixation members.

12. (new) The method of claim 4, wherein the guide slot includes non-threaded interior walls.

13. (new) The method of claim 2, further comprising the step of inserting a first temporary fixation pin into a first pin hole in the plate to temporarily affix the plate to bone.

14. (new) The method of claim 13, further comprising the step of inserting a second temporary fixation pin into a second pin hole in the plate to temporarily affix the plate to bone.

15. (new) The method of claim 14, further comprising the step of axially translating the second fixation pin within the second pin hole during compression of the first and second bones.

16. (new) The method of claim 15, wherein the second pin hole is an elongate slot.

17. (new) The method of claim 3, wherein the angled member is a tab.

18. (new) A method of fusing together first and second bone parts, the method comprising:

forming a cavity in at least one of the first and second bone parts;

associating a bone plate with the first and second bone parts, such that the bone plate spans across the first and second bone parts and at least a first hole of the bone plate is aligned with the first bone part;

inserting a first fixation member through the first hole and into the first bone part;

positioning an angled member of the plate at least partially within the cavity, the angled member including a second hole and being recessed below a top surface of the plate and extending downward at an angle with respect to a bottom surface of the plate; and

inserting a second fixation member through the second hole, into the first bone part, across a divide between the bone parts, and into the second bone part.

19. (new) The method of claim 18, wherein the bone plate includes holes for fixation members on either side of the angled member.

20. (new) The method of claim 18, wherein the second fixation member, once inserted through the second hole of the angled member, extends only into bone and not through another hole in the plate.

21. (new) The method of claim 18, wherein insertion of the second fixation member through the second hole includes inserting the second fixation member through a guide slot in the plate arranged above the second hole and on a trajectory which extends through the second hole.

22. (new) The method of claim 21, wherein the guide slot includes non-threaded interior walls.

23. (new) The method of claim 21, further comprising inserting a third fixation member through a third hole in the plate and into at least one of the first and second bone parts.

24. (new) The method of claim 18, wherein the first and second bone parts are separated by a joint, and the method further comprises inserting a third fixation member through a third hole in the plate and into the second bone part.

25. (new) The method of claim 24, wherein insertion of the second fixation member through the second hole includes inserting the second fixation member across the joint.

26. (new) The method of claim 18, wherein the first hole is a locking hole.

27. (new) The method of claim 18, wherein a central axis of the second hole diverges from a central axis of the first hole.

28. (new) The method of claim 27, further comprising associating a template of the bone plate with at least one of the first and second bone parts to determine the positioning of the angled member.

29. (new) The method of claim 28, wherein the template does not include an angled member.

30. (new) The method of claim 18, wherein the plate includes a set of pin holes adapted to receive temporary fixation pins, a first of the pin holes having an axis extending into the first bone part, and a second of the pin holes having an axis extending into the second bone part.

31. (new) The method of claim 30, further comprising inserting first and second temporary fixation pins into each of the first and second pin holes, and axially translating the second fixation pin within the second pin hole during compression of the first and second bone parts.

32. (new) The method of claim 21, wherein the angled member is angled by about between 30° and 60° with respect to a longitudinal axis of the plate.

33. (new) A method of fusing a joint, the method comprising:

spanning first and second bones separated by a joint with a bone plate, such that a first hole of the bone plate is aligned with a first bone of the joint and a second hole of the bone plate is aligned with a second bone of the joint;

inserting a first fixation member through the first hole of the plate and into the first bone of the joint;

inserting a second fixation member through the second hole of the plate and into the second bone of the joint; and

inserting a third fixation member through a third hole in the plate, into the first bone, across the joint, and into the second bone, the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate, wherein the third fixation member is the only fixation member extending across the joint.

34. (new) The method of claim 33, wherein the third hole is angled by about between 30° and 60° with respect to the longitudinal axis of the plate.

35. (new) The method of claim 33, wherein the first and second holes are locking holes.

36. (new) The method of claim 35, wherein the first and second holes are threaded.

37. (new) The method of claim 33, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into first bone while some of the fixation members extend into the second bone.

38. (new) The method of claim 37, wherein the plate is curved so as to adapt to the curvature of at least one of the first and second bones, and the method further comprises inserting a plurality of fixation members into the plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members.

39. The method of claim 38, further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone.

REMARKS

The above-noted cancellation of claim 1, and addition of new claims 2-39, is respectfully submitted prior to initiation of the prosecution of this application in the U.S. Patent and Trademark Office. The above-noted new claims are respectfully submitted in order to more clearly and appropriately claim at least one aspect of the subject matter which Applicants consider to constitute the inventive contribution. No new matter is included in these amendments.

In view of the above, it is respectfully requested that these amendments now be entered, and that prosecution on the merits of this application now be initiated. If, however, for any reason the Examiner does not believe such action can be taken, it is respectfully requested that the Examiner telephone Applicants' attorney at (908) 654-5000 in order to overcome any objections which the Examiner may have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: November 5, 2013

Respectfully submitted,

Electronic signature:
/Brent L. Farese/
Brent L. Farese
Registration No.: 63,617
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14041706 - GAU: 3775
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	First Named Inventor	Bernard Prandi
	Art Unit	3775
	Examiner Name	C. J. Beccia
	Attorney Docket Number	TRAUMA 3.3-647 CON

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	10	7857836		2010-12-28	Huebner et al.	
	11	7819903		2010-10-26	Fraser et al.	
	12	7799061		2010-09-21	Kay et al.	
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	18	7341589		2008-03-11	Weaver et al.	
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 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B./

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	13	7771457		2010-08-10	Kay et al.	
	14	7766948		2010-08-03	Leung	
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	17	7344538		2008-03-18	Myerson et al.	
	18	7341589		2008-03-11	Weaver et al.	
	19	7326218		2008-02-05	Sterett et al.	

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	Attorney Docket Number	TRAUMA 3.3-647 CON

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	49	20080015593		2008-01-17	Pfefferle et al.	
Change(s) applied to document, /M.K./ 6/11/2015	50	20070270850		~~2007-03-13~~ 2007-11-22	~~Huebner~~ Geissler	
	51	20070233106		2007-10-04	Horan et al.	
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	53	20060241609		2006-10-26	Myerson et al.	
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(19) Europäisches Patentamt
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(54) **Plaque d'arthrodese d'une articulation metatarso-phalangienne**

Arthrodeseplatte für ein Zehengrundgelenk

Arthrodesis plate for a metatarsal-phalanges joint

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(73) Titulaire: **Surge Foot**
01000 Bourg en Bresse (FR)

(72) Inventeur: **Arnould, Hervé Charles Marie**
01000 Bourg en Bresse (FR)

(74) Mandataire: **Grand, Guillaume et al**
Cabinet Lavoix
62, rue de Bonnel
68448 Lyon Cedex 03 (FR)

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Description

[0001] La présente invention concerne une plaque d'arthrodèse d'une articulation métatarso-phalangienne, notamment pour l'articulation entre le premier métatarsien et la première phalange du gros orteil. L'invention concerne également une méthode chirurgicale de pose d'une telle plaque d'arthrodèse.

[0002] Lorsqu'une articulation métatarso-phalangienne souffre d'arthrose ou de déformations, dans certains cas iatrogènes, il est fréquent de fusionner le métatarsien et la phalange reliés par cette articulation, c'est-à-dire de bloquer définitivement cette articulation. A cet effet, on utilise généralement une plaque d'arthrodèse, se présentant sous la forme d'un corps allongé globalement plan, mis en place contre les faces supérieures du métatarsien et de la phalange, à cheval sur l'articulation à bloquer. La partie métatarsienne et la partie phalangienne de ce corps comportent respectivement un ou plusieurs trous traversants, dans chacun desquels on introduit, selon une direction globalement verticale, une vis d'ancrage osseux dans, respectivement, le métatarsien et la phalange. Un exemple de ce genre de plaque est donné dans EP-A-1 297 793.

[0003] Ce genre de plaque présente plusieurs inconvénients. En particulier, juste avant d'immobiliser définitivement la plaque contre le métatarsien et la phalange, il est généralement nécessaire de rapprocher ces deux os l'un de l'autre, de manière à les rendre sensiblement jointifs au niveau de leur extrémité en regard, préalablement réséquée. Les gestes chirurgicaux correspondants sont délicats, dans le sens où, tout en maintenant jointifs le métatarsien et la phalange, le chirurgien doit visser fermement à la fois une vis dans la partie métatarsienne du corps de plaque et une autre vis dans la partie phalangienne. Les risques d'un positionnement non optimal des deux os à fusionner sont réels, impliquant une éventuelle gêne ultérieure pour le patient. Par ailleurs, la fixation de la plaque tend, à la longue, à s'altérer : lorsque le patient marche, ses articulations métatarso-phalangiennes sont soumises à un mouvement de flexion lié à l'appui progressif de sa voûte plantaire, depuis le talon jusqu'aux orteils. Pour l'articulation bloquée par la plaque, la contrainte de flexion est essentiellement encaissée par cette plaque, ce qui, par répétition cyclique de cette contrainte, fragilise l'ancrage osseux des vis retenant la plaque contre les os fusionnés.

[0004] Le but de la présente invention vise à remédier à ces inconvénients, en proposant une plaque d'arthrodèse dont la fixation est simple et pérenne.

[0005] A cet effet, l'invention a pour objet une plaque d'arthrodèse d'une articulation métatarso-phalangienne, telle que définie à la revendication 1.

[0006] La patte de la plaque selon l'invention permet de fixer la plaque sur une face latérale de l'épiphyse de la phalange, c'est-à-dire, anatomiquement parlant, sur la face médiale de la base phalangienne. Cette zone épiphysaire de l'os est généralement solide, permettant la mise en place d'un moyen d'ancrage s'enfonçant profondément dans la matière osseuse. En pratique, lorsque la plaque selon l'invention est implantée au niveau de l'articulation reliant le premier métatarsien et la première phalange du gros orteil, cette patte est fixée à la face interne de l'épiphyse phalangienne, c'est-à-dire la face osseuse dirigée vers le plan sagittal médian du patient, notamment car cette face présente un abord chirurgical aisé. De plus, cette patte est conformée pour que son trou d'extrémité puisse recevoir une vis longue, ou plus généralement un moyen allongé d'ancrage osseux, qui va s'étendre à la fois à travers la matière osseuse de la phalange et dans la matière osseuse du métatarsien, en particulier dans les épiphyses en regard de ces os. On comprend que cette vis longue s'étend en longueur dans une direction présentant une composante antéro-postérieure, de sorte que cette vis encaisse essentiellement, voire exclusivement les contraintes de flexion générées lors de la marche du patient, étant remarqué que, en raison de sa position, la vis travaille principalement en traction. Comme cette vis présente, de par sa structure et sa zone d'implantation, une capacité à s'opposer aux contraintes de flexion nettement plus élevée que celle du corps de la plaque, l'implantation de la plaque est stable dans le temps. Par ailleurs, lors de l'introduction de la vis longue dans le trou d'extrémité de la patte, cette vis tend à générer d'elle-même un effet de rappel du métatarsien vers la phalange lorsque la pointe de la vis atteint et progresse dans la matière osseuse du métatarsien. D'un seul geste, consistant à visser intégralement cette vis longue, le chirurgien rapproche ainsi automatiquement les deux os à fusionner l'un de l'autre, puis il immobilise totalement le corps de plaque sur le métatarsien pour bloquer l'articulation. On comprend que les deux os rendus ainsi jointifs sont fixés l'un par rapport à l'autre de manière prédéterminée, en fonction de la direction dans laquelle le chirurgien introduit la vis longue dans le trou d'extrémité de la patte conforme à l'invention. Ce trou aide donc le chirurgien, dans le sens où il lui fixe le point d'application de la vis, tout en limitant le risque que la pointe de cette vis s'en écarte, notamment par ripement contre la face latérale de la phalange.

[0007] D'autres caractéristiques avantageuses de cette plaque d'arthrodèse, prises isolément ou suivant toutes les combinaisons techniquement possibles, sont énoncées aux revendications 2 à 10.

[0008] L'invention a également pour objet une méthode de pose d'une plaque d'arthrodèse d'une articulation métatarso-phalangienne, laquelle plaque comporte un corps de plaque allongé muni d'une patte allongée qui s'étend en longueur depuis un côté longitudinal du corps de plaque et qui est pourvue, à son extrémité longitudinale opposée au corps de plaque, d'un trou traversant, ladite méthode comprenant les gestes chirurgicaux successifs consistant à :

- inciser et dégager des parties molles entourant l'articulation à bloquer par arthrodèse,

- mettre en place le corps de plaque sur les faces supérieures du métatarsien et de la phalange reliés par l'articulation, de manière que le trou de la patte débouche sur une face latérale de l'épiphyse de la phalange,
- immobiliser partiellement le corps de plaque sur le métatarsien, en autorisant une liberté de mouvements relatifs suivant globalement la direction longitudinale du corps de plaque,
- introduire un moyen allongé d'ancrage osseux dans le trou de la patte, tel qu'une vis longue, et ancrer ce moyen dans successivement l'épiphyse de la phalange et le métatarsien, jusqu'à ce qu'une tête d'extrémité du moyen d'ancrage vienne buter contre la patte, au niveau du bord de son trou,
- poursuivre l'ancrage du moyen d'ancrage de manière à provoquer le rapprochement du métatarsien de la phalange, par un déplacement du métatarsien par rapport au corps de plaque suivant globalement la direction longitudinale de ce corps de plaque,
- immobiliser définitivement le corps de plaque sur le métatarsien et la phalange, et
- fermer l'incision.

[0009] Suivant une caractéristique avantageuse de cette méthode, on fixe le corps de plaque sur la face supérieure de la phalange soit avant, soit après avoir immobilisé partiellement le corps de plaque sur le métatarsien.

[0010] L'invention sera mieux comprise à la lecture de la description qui va suivre, donnée uniquement à titre d'exemple et faite en se référant aux dessins sur lesquels :

- la figure 1 est une vue en perspective d'une plaque d'arthrodèse selon l'invention, mise en place et fixée sur une articulation métatarso-phalangienne bloquée par la plaque ;
- la figure 2 est une vue de la plaque de la figure 1, observée selon la flèche II de la figure 1, qui correspond à une direction d'observation sensiblement verticale ;
- les figures 3 à 6 sont des vues en élévation, prises respectivement selon les flèches III à VI de la figure 2 ; et
- la figure 7 est une coupe partielle de la plaque, selon la ligne VII-VII de la figure 2.

[0011] Sur la figure 1 est représentée une plaque 1 d'arthrodèse d'une articulation entre le premier métatarsien M et la première phalange P du gros orteil d'un pied gauche. Par commodité, la suite de la description est orientée par rapport au patient dont les os du gros orteil sont représentés à la figure 1, ce patient se tenant debout sur un sol horizontal. Ainsi, les termes « inférieur » et « bas » désignent une direction sensiblement verticale dirigée vers le sol, tandis que les termes « supérieur » et « haut » désignent une direction de sens opposé. De même, le terme « intérieur » désigne une direction sensiblement horizontale dirigée vers le plan sagittal médian du patient, tandis que le terme « extérieur » désigne une direction de sens opposé. Les termes « avant », « arrière » et analogues s'entendent également par rapport au patient.

[0012] En pratique, la plaque 1 considérée aux figures appartient avantageusement à un jeu de plusieurs plaques d'arthrodèse, ayant des tailles respectives sensiblement homothétiques. La plaque 1 représentée est la plus appropriée au patient, notamment à la taille de son métatarsien M et de sa phalange P.

[0013] La plaque 1 comporte essentiellement, d'une part, un corps de plaque 10 présentant une forme allongée suivant une direction globalement antéro-postérieure et, d'autre part, une patte allongée intérieure 20.

[0014] Comme représenté plus en détail sur les figures 2 à 7, dans la configuration d'implantation de la plaque 1, le corps de plaque 10 inclut successivement, suivant sa direction longitudinale 11, une partie métatarsienne 12 et une partie phalangienne 13, qui sont respectivement adaptées pour être mises en place et fixées sur le métatarsien M et la phalange P, avec leur face inférieure plaquée contre, respectivement, les surfaces supérieures du métatarsien et de la phalange. La zone 14 de jonction entre les parties 12 et 13 est prévue pour surplomber la zone de jointement entre les extrémités épiphysaires en regard M_1 et P_1 du métatarsien M et de la phalange P, de sorte que le corps de plaque 10 s'étend à cheval sur l'articulation métatarso-phalangienne selon la direction 11.

[0015] Sur le côté longitudinal intérieur 10A du corps de plaque 10, la partie métatarsienne 12 comprend une section cintrée 12_1 reliée à la zone de jonction 14 par une section sensiblement plane 12_2 de cette partie 12. Ces sections 12_1 et 12_2 sont pliées l'une par rapport à l'autre le long d'une ligne de pliage 12_3 s'étendant dans le prolongement rectiligne de la flèche III. La surface inférieure concave 12_{1A} de la section cintrée 12_1, bien visible à la figure 3, est conformée pour épouser la face supérieure de la partie diaphysaire M_2 du métatarsien M, c'est-à-dire pour venir au contact de cette diaphyse, tout en la recouvrant partiellement de manière ajustée, comme représenté sur la figure 1. La surface inférieure sensiblement plate 12_{2A} de la section plane 12_2 est prévue pour recouvrir la zone dorsale de la diaphyse métatarsienne M_2 et, surtout, l'épiphyse métatarsienne M_1 qui a été réséquée préalablement à la mise en place de la plaque. Autrement dit, on comprend que la surface 12_{2A} est prévue pour être mise en place contre une zone surfacique globalement plate de la face supérieure du métatarsien M, tandis que la surface 12_{1A} recouvre une zone métatarsienne bombée.

[0016] Eu égard à la forme anatomique du métatarsien M, la ligne de pliage 12_3 forme, selon la direction d'observation de la flèche II, un angle γ_M non nul avec la direction longitudinale 11 du corps de plaque 10. Avantageusement, pour permettre un bon ajustement des sur-

faces inférieures 12_{1A} et 12_{2A} avec la face supérieure du métatarsien, cet angle γ_M est compris entre 10 et 20°, étant remarqué que des valeurs homothétiques de γ_M sont avantageusement prévues entre les bornes 12° et 18° pour le jeu des plaques de tailles respectives différentes.

[0017] Également sur le côté longitudinal intérieur 10A du corps de plaque 10, la partie phalangienne 13 comprend une section cintrée 13_1 reliée à la zone de jonction 14 par une section sensiblement plane 13_2 de cette partie 13. Ces sections 13_1 et 13_2 sont pliées l'une par rapport à l'autre selon une ligne de pliage 13_3 qui s'étend dans le prolongement rectiligne de la flèche IV. Par analogie avec les explications précédentes concernant les sections 12_1 et 12_2 de la partie métatarsienne 12, on comprend que la surface inférieure concave 13_{1A} de la section cintrée 13_1, bien visible à la figure 4, est dimensionnée pour venir épouser la face médiale bombée de la diaphyse phalangienne P_2, tandis que la surface inférieure 13_{2A} de la section 13_2 recouvre la face dorsale de cette diaphyse et, surtout, l'épiphyse phalangienne P_1, comme représenté à la figure 1.

[0018] Pour des raisons anatomiques, la ligne de pliage 13_3 est, selon la direction d'observation correspondant à la flèche II, inclinée par rapport à la direction 11, en formant avantageusement avec cette dernière un angle non nul γ_P compris entre 15 et 25°. De préférence, l'angle γ_P est égal à 20° +/- 1°.

[0019] Selon la direction d'observation correspondant à la flèche II, les lignes de pliage 12_3 et 13_3 forment globalement un V dont la pointe est dirigée vers l'intérieur.

[0020] Selon une direction d'observation médio-latérale, comme celle correspondant à la flèche V, on note que les sections planes métatarsienne 12_2 et phalangienne 13_2 ne s'étendent pas dans le prolongement rectiligne l'une de l'autre, mais forment au contraire un angle non nul, noté α à la figure 5. A cet effet, les parties métatarsienne 12 et phalangienne 13 sont pliées l'une par rapport à l'autre au niveau de leur zone de jonction 14, selon une ligne de pliage 14_1 sensiblement perpendiculaire à la direction longitudinale 11. Grâce à cette disposition, la partie phalangienne 13 est inclinée vers le haut dans un plan vertical par rapport à la partie métatarsienne 12, ce qui garantit une meilleure adaptation du corps de plaque 10 à l'anatomie de l'articulation métatarso-phalangienne lorsqu'elle est bloquée. En effet, la phalange P est alors immobilisée par rapport au métatarsien M avec un angle de dorsi-flexion non nul, correspondant à l'angle α.

[0021] Pour permettre la fixation du corps de plaque 10 au métatarsien M et à la phalange P, ce corps est pourvu d'une série de trous traversants, adaptés chacun pour recevoir de manière complémentaire une vis d'ancrage osseux ou un moyen mécanique analogue. Avantageusement, chacune des sections 12_1, 12_2, 13_1 et 13_2 est munie d'au moins un de ces trous, respectivement référencés 15_1, 15_2, 15_3 et 15_4. De la sorte, lors du vissage de vis dans ces trous, les surfaces inférieures respectives 12_{1A}, 12_{2A}, 13_{1A} et 13_{2A} de ces sections sont fermement appliquées contre les os.

[0022] La partie métatarsienne 12 est en outre munie d'un orifice traversant 16 de forme oblongue, dont la direction longitudinale est sensiblement parallèle à la direction longitudinale 11 du corps de plaque 10. L'intérêt de cet orifice oblong sera mis en évidence plus loin, lors de la description de la pose de la plaque d'arthrodèse 1.

[0023] La patte 20, également située du côté longitudinal intérieur 10A du corps de plaque 10, s'étend en longueur depuis la partie phalangienne 13. Comme représenté à la figure 1, cette patte est conformée pour envelopper l'épiphyse phalangienne P_1, au plus proche de la matière osseuse, incluant son extrémité libre 22, c'est-à-dire son extrémité longitudinale opposée au corps de plaque 10. La patte 20 donne ainsi l'impression de plonger vers le bas par rapport au corps de plaque 10, de manière que son extrémité 22, située verticalement au-dessous de ce corps de plaque dans la configuration d'implantation de la plaque 1, soit plaquée contre la face latérale intérieure de l'épiphyse phalangienne P_1.

[0024] A cet effet, la patte 20 est pliée vers le bas par rapport au corps de plaque 10 le long d'une ligne de pliage 23 sensiblement perpendiculaire à la direction longitudinale 21 et située au niveau de la jonction entre la patte et la partie phalangienne 13. La patte 20 est également pliée sur elle-même selon une autre ligne de pliage 24 sensiblement perpendiculaire à la direction 21 et située à la jonction entre son extrémité 22 et le reste de la plaque. La forme pliée de la patte 20 est bien visible à la figure 6, dont la direction d'observation, qui correspond à la flèche VI de la figure 2, est alignée avec la ligne de pliage 23.

[0025] Selon la direction d'observation correspondant à la flèche II, la patte 20 est inclinée par rapport au corps de plaque 10 : sa direction longitudinale 21 forme un angle non nul β avec la direction longitudinale 11 du corps de plaque, comme indiqué à la figure 2. Pour des raisons anatomiques, cet angle β est compris entre 20 et 60°. De préférence, l'angle β est égal à 40° +/- 1 °, ce qui permet de disposer de la patte 20 sans que cette dernière ne limite trop l'étendue transversale de la partie phalangienne 13, tout en enveloppant au plus près l'épiphyse phalangienne P_1.

[0026] A son extrémité 22, la patte 20 est pourvue d'un trou traversant 25 adapté pour recevoir une vis 30 ou, plus généralement, un moyen allongé d'ancrage osseux analogue. Cette vis 30 est une vis longue dans le sens où, comme représenté en pointillés à la figure 1, elle présente une longueur suffisante pour s'étendre depuis le trou 25 à la fois dans l'épiphyse phalangienne P_1 et dans l'épiphyse métatarsienne M_1, voire également dans la diaphyse métatarsienne M_2.

[0027] Le trou 25 est prévu pour recevoir la vis 30 de sorte que, selon la direction d'observation correspondant à la flèche II, l'axe longitudinal 31 de cette vis puisse être incliné par rapport à la direction longitudinale 11 du corps

de plaque 10, en formant avec cette direction 11 un angle non nul δ. On comprend que plus cet angle δ est petit, plus l'axe 31 de la vis 30 tend à s'aligner avec une direction antéro-postérieure, garantissant une profondeur de pénétration de la vis dans le métatarsien plus importante, à longueur de vis donnée. En pratique, pour permettre de visser et de bloquer la vis 30 avec son axe 31 incliné par rapport à l'axe central 25_1 du trou 25, le bord 25_2 de ce trou présente, du côté tourné vers la tête 32 de la vis, une surface concave, sensiblement complémentaire d'une surface associée délimitée par cette tête de vis. De la sorte, lorsque la vis 31 est totalement introduite dans le trou 25, sa tête 32 vient prendre appui et se coincer contre au moins une portion du bord 25_2, même si son axe 31 est incliné par rapport à l'axe 25_1 du trou.

[0028] Pour des raisons anatomiques, l'angle δ est avantageusement choisi inférieur à 45°. Dans l'exemple considéré aux figures, cet angle vaut environ 20°.

[0029] Sur son côté longitudinal extérieur 10B, le corps de plaque 10 est chanfreiné, comme représenté à la figure 7. Le chanfrein correspondant 17, globalement plat, est tourné vers le haut dans la configuration d'implantation de la plaque 1. De la sorte, lorsque la plaque est implantée, les risques que cette dernière gêne, voire ne presse significativement le tendon extenseur de l'articulation métatarso-phalangienne sont limités.

[0030] Une méthode de pose de la plaque d'arthrodèse 1 est la suivante. Après avoir incisé et dégagé les parties molles entourant l'articulation à bloquer, le chirurgien résèque en partie les épiphyses métatarsienne M_1 et phalangienne P_1, afin de supprimer des irrégularités osseuses telles que des renflements d'arthrose présents dans l'articulation.

[0031] Après avoir choisi, parmi le jeu de plusieurs plaques d'arthrodèse homothétiques, la plaque 1 dont la taille est la plus appropriée au patient opéré, le chirurgien met ensuite en place la plaque sur les os M et P : le corps de plaque 10 est placé sur les faces supérieures de ces os, tandis que l'extrémité 22 de la patte 20 est placée contre la face latérale intérieure de l'épiphyse phalangienne P_1, c'est-à-dire, anatomiquement, sa face médiale. Le corps de plaque 10 est ensuite partiellement immobilisé en utilisant l'orifice oblong 16 : le chirurgien introduit une vis 2 (figure 1) dans l'orifice 16, du côté du fond arrière 16_2 de cet orifice, sans serrer la tête de vis contre le bord de l'orifice. De la sorte, le corps de plaque 10 reste déplaçable selon la direction 11 par rapport au métatarsien M.

[0032] La vis 30 est ensuite introduite dans le trou 25, suivant une direction d'introduction inclinée par rapport au corps de plaque 10 sous l'angle δ dont la valeur est choisie par le chirurgien pour que cette vis, lors de son vissage, traverse successivement l'épiphyse phalangienne P_1 et l'épiphyse métatarsienne M_1, comme expliqué plus haut. Le vissage de la vis 30 est poursuivi jusqu'à ce que la tête 32 de cette vis vienne buter, selon son axe 31, contre le bord 25_2 du trou 25. En poursuivant le vissage, la vis 30 provoque le rapprochement du métatarsien M par rapport à la phalange P, ce mouvement de rapprochement étant guidé le long de la direction 11 par la coopération de l'orifice oblong 16 et de la vis non serrée 2. Le fond avant 16_1 de l'orifice 16 progresse alors vers l'arrière vis-à-vis de la vis 2, qui se retrouve alors progressivement du côté de ce fond avant 16_1. Le chirurgien poursuit ainsi le vissage de la vis 30 jusqu'à rendre sensiblement jointifs les extrémités épiphysaires M_1 et P_1 des os. On comprend que la direction d'introduction de la vis 30 dans le trou 25 conditionne le positionnement relatif du métatarsien et de la phalange à leur fusion.

[0033] La vis 2 est ensuite totalement vissée et serrée dans l'orifice 16, de manière à immobiliser complètement le corps de plaque 10 sur le métatarsien M. Cette fixation est renforcée en vissant des vis 3 dans les trous 15_1 et 15_2.

[0034] Avant ou après avoir ainsi immobilisé le corps de plaque 10 vis-à-vis du métatarsien M, d'autres vis 4 sont introduites dans les trous 15_3 et 15_4, de manière à fixer la partie phalangienne 13 sur la phalange P.

[0035] Le chirurgien ferme enfin l'incision.

[0036] En pratique, le chirurgien dispose bien entendu de plaques d'arthrodèse pour articulation métatarso-phalangienne du pied droit : ces plaques présentent une structure symétrique à celle de la plaque 1 par rapport à un plan vertical médian à cette dernière.

[0037] Avantageusement, pour faciliter le choix de la taille de la plaque à implanter, le chirurgien dispose en outre d'un jeu de fantômes de plaque d'arthrodèse : chaque fantôme présente des contours extérieurs identiques à ceux d'une des plaques d'arthrodèse disponibles dans le jeu à sa disposition, de sorte que, après avoir incisé le patient et effectué des premières résections osseuses, le chirurgien met en place l'un de ces fantômes, d'une part, pour sélectionner la taille d'implant la plus appropriée et, d'autre part, pour s'assurer que les résections sont suffisantes, notamment au niveau de la zone de coaptation entre plaque d'une part et métatarsien et phalange d'autre part.

[0038] Par ailleurs, lors de la mise en place de la plaque 1, le chirurgien a avantageusement la possibilité de modifier l'angle α pour ajuster au mieux cet angle avec l'angle anatomique de dorsi-flexion entre le métatarsien M et la phalange P du patient opéré, en tenant compte notamment des résections osseuses et de la morphologie générale des os du patient, ainsi que des habitudes de chaussage et plus particulièrement la hauteur du talon de la chaussure.

[0039] La fabrication de la plaque 1 est réalisée à partir d'une plaque plane métallique. Cette plaque est, dans un premier temps, découpée suivant des contours prédéterminés afin d'obtenir les parties métatarsienne 12 et phalangienne 13, ainsi que la patte 20. Dans un second temps, les différents trous 15_1 à 15_4 et l'orifice oblong 16 sont percés. Dans un troisième temps, les sections 12_1 et 13_1 sont cintrées, tandis que la plaque est pliée le long des lignes 12_3, 13_3, 23 et 24.

[0040] Divers aménagements et variantes à la plaque

1 décrite ci-dessus, ainsi qu'à sa méthode de pose sont envisageables. A titre d'exemples :

- la face inférieure de la plaque est grenaillée ou, de manière plus générale, subit un traitement de surface, afin de favoriser une colonisation osseuse une fois que la plaque est implantée ; et/ou
- le nombre de trous 15_1 à 15_4 peut être modifié, notamment en fonction de la taille longitudinale du corps de plaque 10.

Revendications

1. Plaque (1) d'arthrodèse d'une articulation métatarso-phalangienne, comportant un corps de plaque allongé (10) adapté pour être mis en place et fixé sur les faces supérieures respectives du métatarsien (M) et de la phalange (P) reliés par l'articulation à bloquer par arthrodèse, de manière à s'étendre en longueur à cheval sur l'articulation,
caractérisée en ce que le corps de plaque (10) est muni d'une patte allongée (20) de fixation à une face latérale de l'épiphyse (P_1) de la phalange (P), laquelle patte s'étend en longueur depuis un côté longitudinal (10A) du corps de plaque et est pourvue, à son extrémité longitudinale (22) opposée au corps de plaque, d'un trou traversant (25) adapté pour recevoir un moyen allongé (30) d'ancrage osseux dans, à la fois, la phalange (P) et le métatarsien (M), tel qu'une vis longue.

2. Plaque selon la revendication 1, **caractérisée en ce que**, selon une direction d'observation (flèche II) sensiblement verticale lorsque la plaque (1) est implantée, la patte (20) s'étend suivant une direction longitudinale (21) qui forme avec la direction longitudinale (11) du corps de plaque (10) un angle (β) compris entre 20 et 60°, de préférence égal à 40° +/- 1°.

3. Plaque selon l'une des revendications 1 ou 2, **caractérisée en ce que** le trou traversant (25) de la patte (20) est adapté pour recevoir le moyen d'ancrage osseux (30) dans une position dans laquelle, selon une direction d'observation (flèche II) sensiblement verticale lorsque la plaque (1) est implantée, la direction longitudinale (31) de ce moyen d'ancrage, tel que l'axe central d'une vis longue, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (δ) inférieur à 45°.

4. Plaque selon l'une quelconque des revendications précédentes, **caractérisée en ce que** la patte (20) est pliée selon au moins une ligne de pliage (23, 24) sensiblement perpendiculaire à la direction longitudinale (21) de la patte.

5. Plaque selon l'une quelconque des revendications précédentes, **caractérisée en ce que** le corps de plaque (10) comprend, suivant sa longueur, une partie métatarsienne (12) et une partie phalangienne (13), respectivement adaptées pour être mises en place et fixées sur les faces supérieures du métatarsien (M) et de la phalange (P), et **en ce que** la patte (20) s'étend depuis la partie phalangienne (13), en étant de préférence monobloc avec cette dernière.

6. Plaque selon la revendication 5, **caractérisée en ce que** la partie métatarsienne (12) est pourvue d'un orifice traversant oblong (16) dont la direction longitudinale est sensiblement parallèle à la direction longitudinale (11) du corps de plaque (10).

7. Plaque selon l'une des revendications 5 ou 6, **caractérisée en ce que** la, partie métatarsienne (12) inclut, d'une part, du même côté longitudinal (10A) du corps de plaque (10) que la patte (20), une section cintrée (12_1), dont la face concave (12_{1A}) est adaptée pour venir au contact et pour envelopper la face supérieure bombée de la diaphyse métatarsienne (M_2), et, d'autre part, une section sensiblement plane (12_2) reliant la section cintrée à la partie phalangienne (13).

8. Plaque selon la revendication 7, **caractérisée en ce que** la section cintrée (12_1) et la section sensiblement plane (12_2) de la partie métatarsienne (12) sont pliées l'une par rapport à l'autre selon une ligne de pliage (12_3) qui, selon une direction d'observation (flèche II) sensiblement verticale lorsque la plaque (1) est implantée, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (γ_M) compris entre 10 et 20°, des valeurs homothétiques de cet angle étant de préférence prévues entre les bornes 12° et 18° pour un jeu de plaques d'arthrodèse présentant des tailles respectives différentes.

9. Plaque selon l'une quelconque des revendications 5 à 8, **caractérisée en ce que** la partie phalangienne (13) inclut, d'une part, du même côté longitudinal (10A) du corps de plaque (10) que la patte (20), une section cintrée (13_1), dont la face concave (13_{1A}) est adaptée pour venir au contact et pour envelopper la face supérieure bombée de la diaphyse phalangienne (P_2), et, d'autre part, une section sensiblement plane (13_2) reliant la section cintrée à la partie métatarsienne (12).

10. Plaque selon la revendication 9, **caractérisée en ce que** la section cintrée (13_1) et la section sensiblement plane (13_2) de la partie phalangienne (13) sont pliées l'une par rapport à l'autre selon une ligne de pliage (13_3) qui, selon une direction d'observation (flèche II) sensiblement verticale lorsque la plaque

(1) est implantée, forme avec la direction longitudinale (11) du corps de plaque (10) un angle (γ_P) compris entre 15 et 25°, de préférence égal à 20° +/-1°.

Claims

1. Arthrodesis plate (1) for a metatarsophalangeal joint, comprising an elongated plate body (10) adapted to be put in place and fixed on the respective top faces of the metatarsal (M) and phalange (P) connected by the joint to be locked by arthrodesis so as to extend lengthwise straddling the joint, **characterised in that** the plate body (10) is fitted with an elongated leg (20) for fixing to a lateral face of the epiphysis (P_1) of the phalange (P), which leg extends lengthwise from a longitudinal side (10A) of the plate body and at the longitudinal end (22) opposite the plate body is provided with a through hole (25) adapted to take an elongated means (30) of osseous anchorage in the phalange (P) and metatarsal (M) at the same time, such as a long screw.

2. Plate according to claim 1, **characterised in that** according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, the leg (20) extends in a longitudinal direction (21), which forms an angle (β) of between 20 and 60°, preferably equal to 40° +/-1°, with the longitudinal direction (11) of the plate body (10).

3. Plate according to one of claims 1 or 2, **characterised in that** the through hole (25) of the leg (20) is adapted to take the means of osseous anchorage (30) in a position, in which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, the longitudinal direction (31) of this means of anchorage, such as the central shaft of a long screw, forms an angle (δ) of less than 45° with the longitudinal direction (11) of the plate body (10).

4. Plate according to any one of the previous claims, **characterised in that** the leg (20) is folded according to at least one folding line (23, 24) more or less perpendicular to the longitudinal direction (21) of the leg.

5. Plate according to any one of the previous claims, **characterised in that** along its length the plate body (10) comprises a metatarsal part (12) and a phalangeal part (13), adapted to be put in place and fixed on the top faces of the metatarsal (M) and phalange (P) respectively, and **in that** the leg (20) extends from the phalangeal part (13), preferably forming a solid block with it.

6. Plate according to claim 5, **characterised in that** the metatarsal part (12) is provided with an oblong through hole (16), the longitudinal direction of which is more or less parallel to the longitudinal direction (11) of the plate body (10).

7. Plate according to one of claims 5 or 6, **characterised in that** the metatarsal part (12) includes on the one hand, on the same longitudinal side (10A) of the plate body (10) as the leg (20), an arched section (12_1), the concave face (12_{1A}) of which is adapted to come into contact and surround the top convex face of the metatarsal diaphysis (M_2), and on the other hand a more or less flat section (12_2) connecting the arched section to the phalangeal part (13).

8. Plate according to claim 7, **characterised in that** the arched section (12_1) and the more or less flat section (12_2) of the metatarsal part (12) are folded in relation to each other according to a folding line (12_3), which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, forms an angle (γ_M) of between 10 and 20° with the longitudinal direction (11) of the plate body (10), homothetical values of this angle preferably being provided between the limits of 12° and 18° for a set of arthrodesis plates of different respective sizes.

9. Plate according to any one of claims 5 to 8, **characterised in that** the phalangeal part (13) includes on the one hand, on the same longitudinal side (10A) of the plate body (10) as the leg (20), an arched section (13_1), the concave face (13_{1A}) of which is adapted to come into contact and surround the top convex face of the phalange diaphysis (P_2), and on the other hand a more or less flat section (13_2) connecting the arched section to the metatarsal part (12).

10. Plate according to claim 9, **characterised in that** the arched section (13_1) and the more or less flat section (13_2) of the phalangeal part (13) are folded in relation to each other according to a folding line (13_3), which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, forms an angle (γ_P) of between 15 and 25°, preferably equal to 20° +/-1°, with the longitudinal direction (11) of the plate body (10).

Patentansprüche

1. Arthrodeseplatte (1) für ein metatarsophalangeales Gelenk, umfassend einen langgestreckten Plattenkörper (10), der dafür eingerichtet ist, an den jeweiligen Oberseiten des Metatarsalknochens (M) und der Phalanx (P), die durch das mittels Arthrodese zu blockierende Gelenk verbunden sind, angebracht und befestigt zu werden, derart, dass er sich in

Längsrichtung auf dem Gelenk aufsitzend erstreckt, **dadurch gekennzeichnet, dass** der Plattenkörper (10) mit einer langgestreckten Lasche (20) zur Befestigung an einer Seitenfläche der Epiphyse (P_1) der Phalanx (P) ausgestattet ist, wobei sich diese Lasche in Längsrichtung von einer Längsseite (10A) des Plattenkörpers aus erstreckt und an ihrem dem Plattenkörper gegenüberliegenden Längsende (22) mit einem Durchgangsloch (25) versehen ist, das dafür eingerichtet ist, ein langgestrecktes Mittel (30) zur Knochenverankerung gleichzeitig in der Phalanx (P) und dem Metatarsalknochen (M) aufzunehmen, wie etwa eine lange Schraube.

2. Platte nach Anspruch 1, **dadurch gekennzeichnet, dass** in einer im Wesentlichen vertikalen Betrachtungsrichtung (Pfeil II), wenn die Platte (1) implantiert ist, die Lasche (20) sich in einer Längsrichtung (21) erstreckt, welche mit der Längsrichtung (11) des Plattenkörpers (10) einen Winkel (β) bildet, der zwischen 20° und 60° beträgt und vorzugsweise gleich 40° +/- 1° ist.

3. Platte nach einem der Ansprüche 1 oder 2, **dadurch gekennzeichnet, dass** das Durchgangsloch (25) der Lasche (20) dafür eingerichtet ist, das Mittel zur Knochenverankerung (30) in einer Position aufzunehmen, in welcher in einer im Wesentlichen vertikalen Betrachtungsrichtung (Pfeil II), wenn die Platte (1) implantiert ist, die Längsrichtung (31) dieses Verankerungsmittels, wie etwa die Mittelachse einer langen Schraube, mit der Längsrichtung (11) des Plattenkörpers (10) einen Winkel (δ) bildet, der kleiner als 45° ist.

4. Platte nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Lasche (20) entlang mindestens einer Biegelinie (23, 24) umgebogen ist, die im Wesentlichen senkrecht zur Längsrichtung (21) der Lasche ist.

5. Platte nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Plattenkörper (10), in seiner Längsrichtung gesehen, einen metatarsalen Teil (12) und einen phalangealen Teil (13) umfasst, die dafür eingerichtet sind, an der Oberseite des Metatarsalknochens (M) bzw. der Phalanx (P) angebracht und befestigt zu werden, und **dadurch**, dass sich die Lasche (20) von dem phalangealen Teil (13) aus erstreckt, wobei sie vorzugsweise mit Letzterem aus einem Stück besteht.

6. Platte nach Anspruch 5, **dadurch gekennzeichnet, dass** der metatarsale Teil (12) mit einer länglichen durchgehenden Öffnung (16) versehen ist, deren Längsrichtung im Wesentlichen parallel zur Längsrichtung (11) des Plattenkörpers (10) ist.

7. Platte nach einem der Ansprüche 5 oder 6, **dadurch gekennzeichnet, dass** der metatarsale Teil (12) einerseits auf derselben Längsseite (10A) des Plattenkörpers (10), auf der sich die Lasche (20) befindet, einen rundgebogenen Abschnitt (12_1) enthält, dessen konkave Seite (12_{1A}) dafür eingerichtet ist, mit der gewölbten Oberseite der Metatarsalknochendiaphyse (M_2) in Kontakt zu kommen und sie zu umhüllen, und andererseits einen im Wesentlichen ebenen Abschnitt (12_2), der den rundgebogenen Abschnitt mit dem phalangealen Teil (13) verbindet.

8. Platte nach Anspruch 7, **dadurch gekennzeichnet, dass** der rundgebogene Abschnitt (12_1) und der im Wesentlichen ebene Abschnitt (12_2) des metatarsalen Teils (12) relativ zueinander um eine Biegelinie (12_3) umgebogen sind, welche in einer im Wesentlichen vertikalen Betrachtungsrichtung (Pfeil II), wenn die Platte (1) implantiert ist, mit der Längsrichtung (11) des Plattenkörpers (10) einen Winkel (γ_M) bildet, der zwischen 10° und 20° beträgt, wobei homothetische Werte dieses Winkels vorzugsweise zwischen den Begrenzungen 12° und 18° für einen Satz von Arthrodeseplatten vorgesehen sind, die unterschiedliche jeweilige Größen aufweisen.

9. Platte nach einem der Ansprüche 5 bis 8, **dadurch gekennzeichnet, dass** der phalangeale Teil (13) einerseits auf derselben Längsseite (10A) des Plattenkörpers (10), auf der sich die Lasche (20) befindet, einen rundgebogenen Abschnitt (13_1) enthält, dessen konkave Seite (13_{1A}) dafür eingerichtet ist, mit der gewölbten Oberseite der Phalanxdiaphyse (P_2) in Kontakt zu kommen und sie zu umhüllen, und andererseits einen im Wesentlichen ebenen Abschnitt (13_2), der den rundgebogenen Abschnitt mit dem metatarsalen Teil (12) verbindet.

10. Platte nach Anspruch 9, **dadurch gekennzeichnet, dass** der rundgebogene Abschnitt (13_1) und der im Wesentlichen ebene Abschnitt (13_2) des phalangealen Teils (13) relativ zueinander um eine Biegelinie (13_3) umgebogen sind, welche in einer im Wesentlichen vertikalen Betrachtungsrichtung (Pfeil II), wenn die Platte (1) implantiert ist, mit der Längsrichtung (11) des Plattenkörpers (10) einen Winkel (γ_P) bildet, der zwischen 15° und 25° beträgt und vorzugsweise gleich 20° +/- 1° ist.

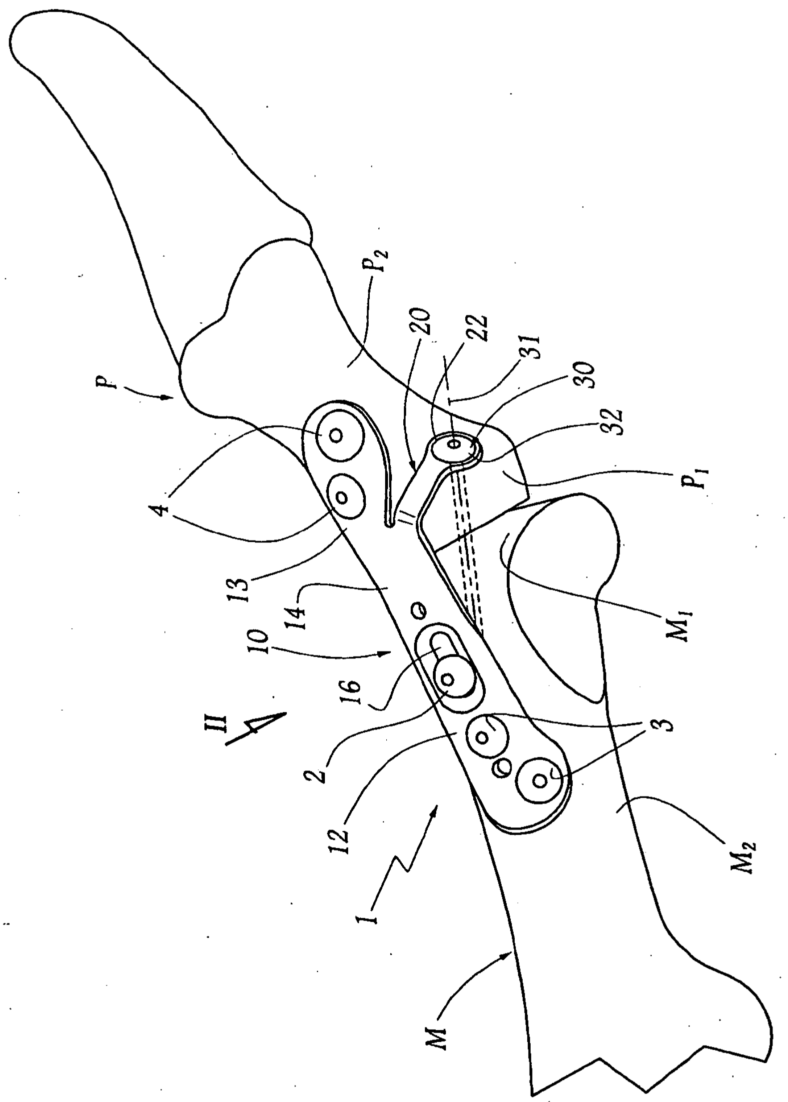


Fig.1

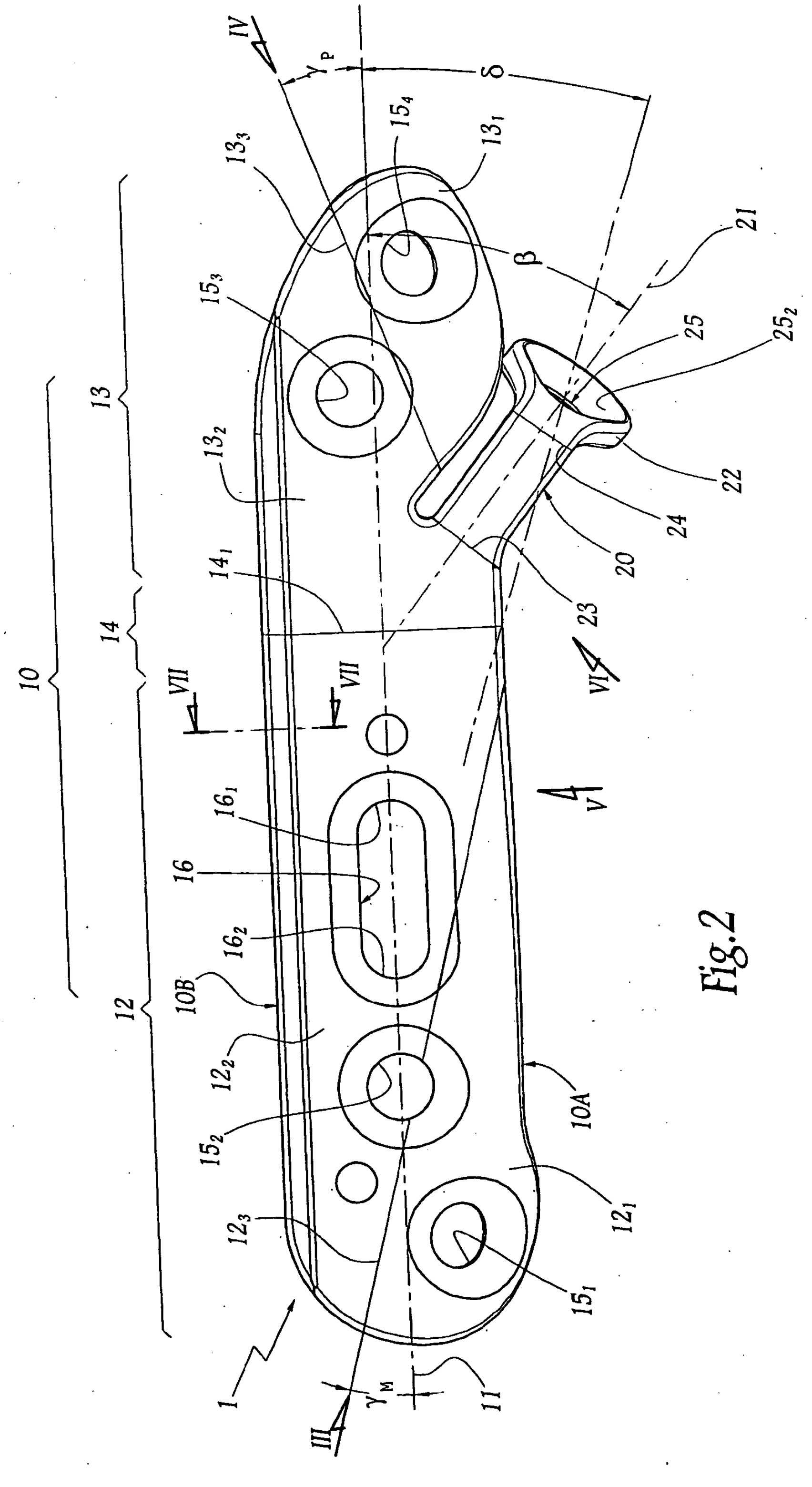
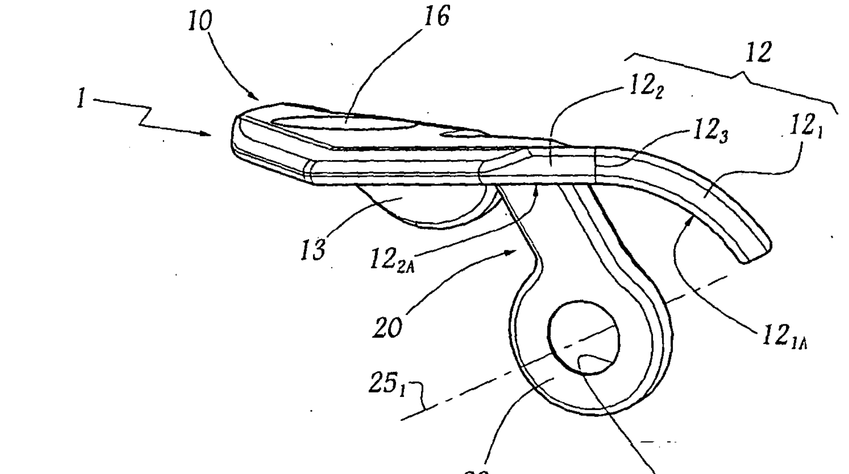
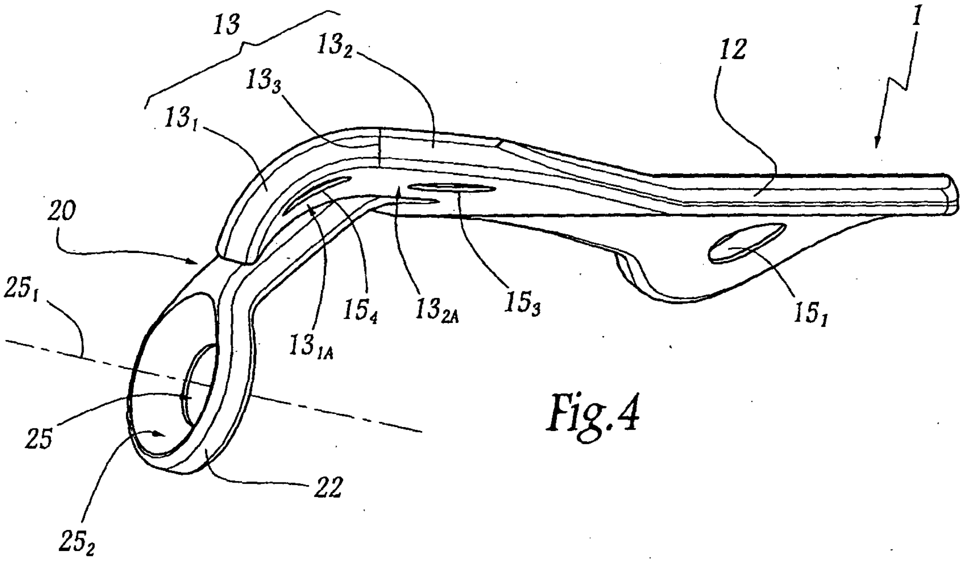

IV
γ_P
δ
15_4
13_1
13_3
21
β
15_3
25
25_2
13
13_2
22
24
20
14_1
23
14
10
VII
VII
VI
V
16_1
16
16_2
10B
12
12_2
10A
15_2
12_1
12_3
15_1
1
γ_M
11
III

Fig.2



10
16
12
1
12_2
12_3
12_1
13
12_{2A}
20
12_{1A}
25_1
22
25

Fig.3



13
13_2
1
12
13_3
13_1
20
25_1
15_4
13_{2A}
15_3
15_1
13_{1A}
25
22
25_2

Fig.4

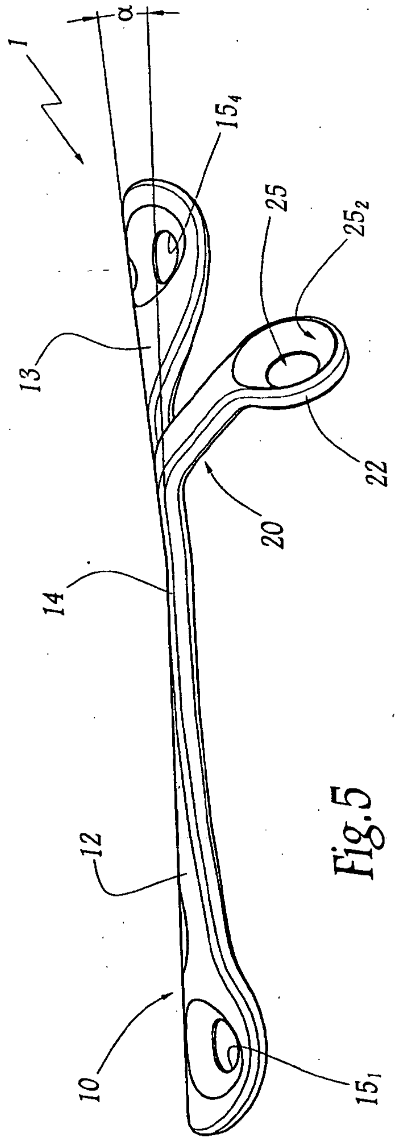


Fig.5

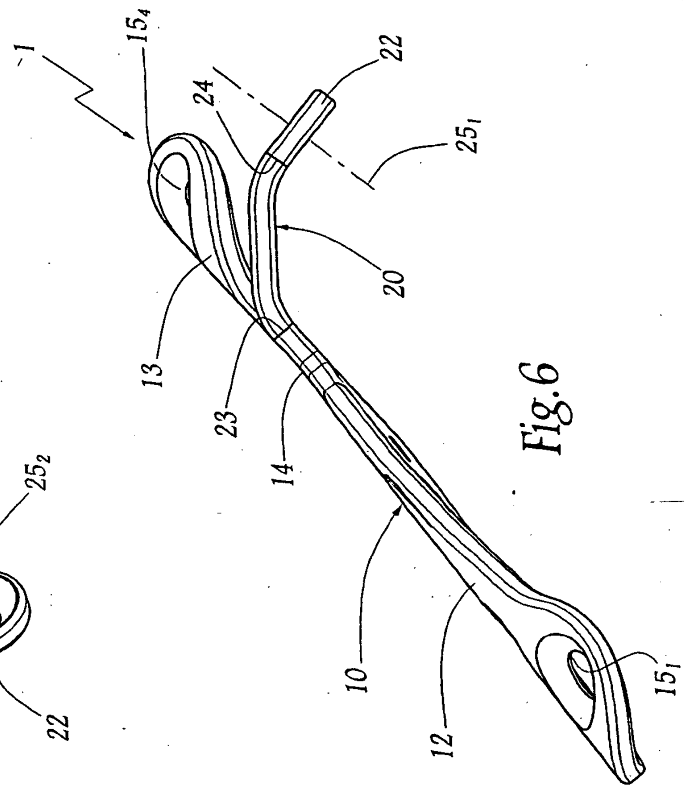


Fig.6

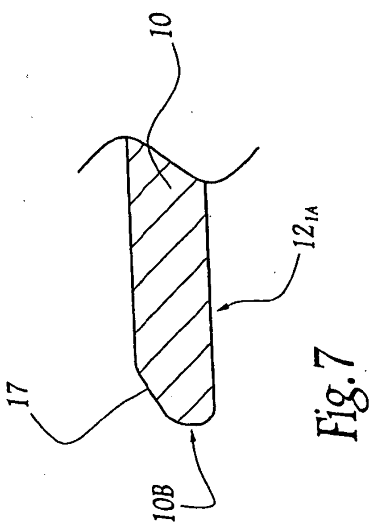


Fig.7

RÉFÉRENCES CITÉES DANS LA DESCRIPTION

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Documents brevets cités dans la description

- EP 1297793 A **[0002]**

(19) Europäisches Patentamt / European Patent Office / Office européen des brevets
/German/
/English/
/French/

(11) **EP 1 897 509 B1**

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(73) Holder: **Surge Foot**
01000 Bourg en Bresse (FR)

(72) Inventor: **Arnould, Hervé Charles Marie**
01000 Bourg en Bresse (FR)

(74) Representative: **Grand, Guillaume et al.**
Cabinet Lavoix
62 Rue de Bonnel
68448 Lyon Cédex 03 (FR)

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EP 1 897 509 B1

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[0001] The present invention relates to an arthrodesis plate for a metatarsal-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe. The invention also relates to a surgical method for placing such an arthrodesis plate.

[0002] When a metatarsal-phalangeal joint suffers from arthrosis or deformities, which are in some cases iatrogenic, it is common to fuse the metatarsal and the phalanx connected by this joint – that is to say, to permanently lock this joint. An arthrodesis plate in the form of an elongated, generally flat body placed against the upper surfaces of the metatarsal and phalanx straddling the joint to be locked, is usually used for this purpose. The metatarsal part and the phalangeal part of this body have one or more corresponding through-holes, into each of which a bone anchoring screw is introduced, in a generally vertical direction, into the metatarsal and the phalanx, respectively. An example of such a plate is given in EP-A-1 297 793.

[0003] This type of plate has several disadvantages. In particular, just before immobilizing the plate permanently against the metatarsal and the phalanx, it is usually necessary to bring these two bones closer to each other in order to make them substantially jointed at the level of their facing extremity, which has previously been resected. The corresponding surgical procedures are delicate in the sense that, while keeping the metatarsal and phalanx together, the surgeon must firmly screw both a screw into the metatarsal part of the plate body and another screw into the phalangeal part. There is a real risk of a non-optimal positioning of the two bones to be fused, which may result in subsequent discomfort for the patient. In addition, the fixation of the plate tends to alternate over the long term: when the patient walks, his metatarsal-phalangeal joints are subjected to a flexion movement linked to the progressive support of his plantar arch, from the heel to the toes. For the joint locked by the plate, the bending stress is essentially absorbed by this plate which, through a cyclical repetition of this stress, weakens the bone anchorage of the screws holding the plate against the fused bones.

[0004] The purpose of the present invention is to remedy these disadvantages by providing an arthrodesis plate with a simple and durable fixation.

[0005] For this purpose, the invention has as its object an arthrodesis plate for a metatarsal-phalangeal joint, as defined in claim 1.

[0006] The leg of the plate in accordance with the invention allows the plate to be attached to a lateral surface of the epiphysis of the phalanx – that is to say, in anatomical terms, to the medial surface of the phalangeal base. This epiphyseal zone of the bone is generally solid, allowing for the placement of an anchoring device that penetrates deep into the bone material. In practice, when the plate in accordance with the invention is implanted at the joint connecting the first metatarsal and the first phalanx of the big toe, this leg is fixed to the medial surface of the phalangeal epiphysis – that is to say, the bone surface directed towards the medial sagittal plane of the patient, particularly because this surface presents an easy surgical approach. Moreover, this leg is shaped so that its end hole can receive a long screw or, more generally, an elongated bone anchoring means which will extend both through the bone material of the phalanx and into the bone material of the metatarsal, particularly into the epiphyses opposite these bones. It can be understood that this long screw extends lengthwise in a direction having an anteroposterior component, so that this screw essentially, if not exclusively, takes up the bending stresses generated during the patient's walking, it being noted that, due to its position, the screw works mainly by means of traction. Since this screw has a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone, the implantation of the plate is stable over time. Furthermore, when the long screw is inserted into the end hole of the foot, it tends to generate a self-recovery effect from the metatarsal to the phalanx when the tip of the screw reaches and progresses into the bone material of the metatarsal. With a single action consisting of screwing in this long screw, the surgeon automatically brings the two bones to be fused closer to each other and then completely immobilizes the plate body on the metatarsal in order to lock the joint. It can be understood that the two bones that are made jointed in this way are fixed in relation to each other in a predetermined manner, depending on the direction in which the surgeon inserts the long screw into the end hole of the leg in accordance with the invention. This hole thus helps the surgeon, in the sense that it fixes the point of application of the screw while limiting the risk of the tip of this screw moving away from it, particularly by skidding against the lateral surface of the phalanx.

[0007] Other advantageous features of this arthrodesis plate, considered alone or in any technically possible combination, are set forth in claims 2 to 10.

[0008] It is also an object of the invention to provide a method for placing a metatarsal-phalangeal joint arthrodesis plate, which plate has an elongated plate body with an elongated

leg extending lengthwise from one longitudinal side of the plate body and provided with a through-hole at its longitudinal end opposite the plate body, with the said method comprising the successive surgical steps of:

- Incising and clearing soft tissue surrounding the joint to be locked by arthrodesis,
- Placing the plate body on the upper surfaces of the metatarsal and phalanx connected by the joint so that the hole in the leg opens onto a lateral surface of the epiphysis of the phalanx,
- Partially immobilizing the plate body on the metatarsal, allowing relative freedom of movement generally along the longitudinal direction of the plate body,
- Inserting an elongated bone anchor into the hole of the leg, such as a long screw, and successively anchoring this anchor in the epiphysis of the phalanx and the metatarsal until an end head of the anchor abuts the leg at the edge of its hole,
- Continuing to anchor the anchoring device in order to bring the metatarsal closer to the phalanx by moving the metatarsal relative to the plate body in the longitudinal direction of the plate body,
- Permanently immobilizing the plate body on the metatarsal and phalanx, and
- Closing the incision.

[0009] In accordance with an advantageous feature of this method, the plate body is attached to the upper surface of the phalanx either before or after the plate body is partially immobilized on the metatarsal.

[0010] The invention will be better understood upon reading the following description, which is provided only by way of example and is drawn up with reference to the drawings, in which:

- Figure 1 is a perspective view of an arthrodesis plate in accordance with the invention placed and fixed on a metatarsal-phalangeal joint locked by the plate;

- Figure 2 is a view of the plate of Figure 1, observed in accordance with arrow II of Figure 1, which corresponds to a substantially vertical direction of observation;

- Figures 3 through 6 are elevation views drawn in accordance with arrows III through VI of Figure 2, respectively; and

- Figure 7 is a partial cross-section of the plate along the line VII-VII of Figure 2.

[0011] Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot. For the sake of convenience, the remainder of the description is oriented in relation to the patient, the bones of whose big toe are shown in Figure 1 with the patient standing on level ground. Thus, the terms “lower” and “bottom” refer to a substantially vertical direction toward the ground, while the terms “upper” and “top” refer to the opposite direction. Similarly, “inside” refers to a substantially horizontal direction toward the patient’s medial sagittal plane, while “outside” refers to the opposite direction. The terms “front”, “back” and the like are also understood in relation to the patient.

[0012] In practice, the plate 1 considered in the figures advantageously belongs to a set of several arthrodesis plates having substantially homothetic respective sizes. The plate 1 depicted is the most appropriate one for the patient, particularly for the size of his metatarsal M and phalanx P.

[0013] The plate 1 essentially comprises, on the one hand, a plate body 10 having an elongated shape in a generally antero-posterior direction and, on the other hand, an elongated internal leg 20.

[0014] As shown in greater detail in Figures 2 to 7 in the configuration of implantation of the plate 1, the plate body 10 successively includes, along its longitudinal direction 11, a metatarsal portion 12 and a phalangeal portion 13 which are respectively adapted to be placed and fixed on the metatarsal M and the phalanx P, with their lower surface plated against the upper surfaces of the metatarsal and phalanx, respectively. The joint zone 14 between parts 12 and 13 is provided to overlie the joint zone between the facing epiphyseal ends M_1 and P_1 of the

metatarsal M and phalanx P so that the plate body 10 straddles the metatarsal-phalangeal joint along direction 11.

[0015] On the inner longitudinal side 10A of the plate body 10, the metatarsal portion 12 includes a curved section 12_1 connected to the junction zone 14 by a substantially planar section 12_2 of that portion 12. These sections 12_1 and 12_2 are bent relative to each other along a bend line 12_3 extending in the straight line extension of arrow III. The concave lower surface 12_{1A} of the bent section 12_1, which is clearly visible in Figure 3, is shaped to conform to the upper surface of the diaphyseal portion M_2 of the metatarsal M – that is to say, to come into contact with this diaphysis while partially covering it in a fitted manner, as shown in Figure 1. The substantially flat lower surface 12_{2A} of the flat section 12_2 is intended to cover the dorsal zone of the metatarsal diaphysis M_2 and, more importantly, the metatarsal epiphysis M_1 that has been resected prior to the placement of the plate. In other words, it can be understood that the surface 12_{2A} is intended to be placed against a generally flat surface zone of the upper surface of the metatarsal M, while surface 12_{1A} covers a domed metatarsal zone.

[0016] In view of the anatomical shape of the metatarsal M, the bending line 12_3 forms, in the direction of observation of arrow II, a non-zero angle γ_M with the longitudinal direction 11 of the plate body 10. Advantageously, in order to allow a good fit of the lower surfaces 12_{1A} and 12_{2A} with the upper surface of the metatarsal, this angle γ_M is between 10 and 20°, it being noted that homothetic values of γ_M are advantageously provided between the terminals 12° and 18° for the play of plates of different respective sizes.

[0017] The phalangeal portion 13 on the inner longitudinal side 10A of the plate body 10 also includes a curved section 13_1 connected to the junction zone 14 by a substantially planar section 13_2 of that part 13. These sections 13_1 and 13_2 are bent relative to each other along a bend line 13_3 which extends in the straight line extension of arrow IV. By analogy with the preceding explanations concerning sections 12_1 and 12_2 of the metatarsal part 12, it can be understood that the concave lower surface 13_{1A} of the bent section 13_1, which is clearly visible in Figure 4, is sized to fit the bulging medial surface of the phalangeal diaphysis P_2, while the lower surface 13_{2A} of the section 13_2 covers the dorsal surface of this diaphysis and, above all, the phalangeal epiphysis P_1, as represented in Figure 1.

[0018] For anatomical reasons, the fold line 13_3 is inclined, along the direction of observation corresponding to arrow II, in relation to direction 11, advantageously forming a non-zero angle γP of between 15 and 25° with the latter. The angle γ_P is preferably equal to 20° ± 1°.

[0019] In the direction of viewing corresponding to arrow II, the fold lines 12_3 and 13_3 generally form a V shape with the tip pointing inward.

[0020] In accordance with a medio-lateral direction of observation, such as the one corresponding to arrow V, it is noted that the metatarsal 12_2 and phalangeal 13_2 planar sections do not extend in the rectilinear extension of each other, but instead form a non-zero angle, noted as α in Figure 5. For this purpose, the metatarsal 12 and phalangeal 13 parts are bent relative to each other at their junction zone 14 along a bending line 14_1 which is substantially perpendicular to the longitudinal direction 11. Because of this arrangement, the phalangeal part 13 is inclined upwards in a vertical plane in relation to the metatarsal part 12, which guarantees a better adaptation of the plate body 10 to the anatomy of the metatarsal-phalangeal joint when it is locked. In point of fact, the phalanx P is then immobilized relative to the metatarsal M with a non-zero dorsi-flexion angle corresponding to the angle α.

[0021] In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner. Each of the sections 12_1, 12_2, 13_1 and 13_2 is advantageously provided with at least one of these holes, which are referenced as 15_1, 15_2, 15_3 and 15_4, respectively. In this way, when screws are screwed into these holes, the respective lower surfaces 12_{1A}, 12_{2A}, 13_{1A} and 13_{2A} of these sections are firmly applied against the bones.

[0022] The metatarsal portion 12 is additionally provided with an oblong through-hole 16, the longitudinal direction of which is substantially parallel to the longitudinal direction 11 of the plate body 10. The value of this oblong hole will be highlighted later when the placement of the arthrodesis plate 1 is described.

[0023] The leg 20, which is also located on the inner longitudinal side 10A of the plate body 10, extends lengthwise from the phalangeal portion 13. As shown in Figure 1, this leg is shaped to wrap around the phalangeal epiphysis P_1 as close as possible to the bone material, including its

free end 22 – that is to say, its longitudinal end opposite the plate body 10. The leg 20 thus gives the impression of plunging downward in relation to the plate body 10, so that its end 22, which is located vertically below this plate body in the configuration of implantation of the plate 1, is pressed against the inner lateral surface of the phalangeal epiphysis P_1.

[0024] For this purpose, the leg 20 is bent downward relative to the plate body 10 along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13. The leg 20 is also folded on itself along another fold line 24 substantially perpendicular to the direction 21 and located at the junction between its end 22 and the rest of the plate. The folded shape of the leg 20 is clearly visible in Figure 6, the direction of viewing of which, which corresponds to arrow VI in Figure 2, is aligned with the fold line 23.

[0025] In the direction of viewing corresponding to arrow II, the leg 20 is inclined in relation to the plate body 10: its longitudinal direction 21 forms a non-zero angle β with the longitudinal direction 11 of the plate body, as shown in Figure 2. For anatomical reasons, this angle β is between 20 and 60°. Preferably, the angle β is equal to 40° ± 1°, which allows the leg 20 to be arranged without limiting the transverse extent of the phalangeal portion 13 too much, while enveloping the phalangeal epiphysis P_1 as closely as possible.

[0026] At its end 22, the leg 20 is provided with a through-hole 25 adapted to receive a screw 30 or, more generally, a similar elongated bone anchoring means. This screw 30 is a long screw in the sense that, as shown by the dotted line in Figure 1, it has sufficient length to extend from the hole 25 into both the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2.

[0027] The hole 25 is provided to receive the screw 30 so that, depending on the direction of observation corresponding to arrow II, the longitudinal axis 31 of this screw can be inclined in relation to the longitudinal direction 11 of the plate body 10, forming a non-zero angle δ with this direction 11. It can be understood that the smaller this angle δ is, the more the axis 31 of the screw 30 tends to align with an anteroposterior direction, guaranteeing a greater depth of penetration of the screw into the metatarsal for any given length of screw. In practice, in order to allow the screw 30 to be screwed in and locked with its axis 31 inclined in relation to the central axis 25_1 of the hole 25, the edge 25_2 of this hole has, on the side facing the head 32 of the

screw, a concave surface which is substantially complementary to an associated surface delimited by this screw head. In this way, when the screw 31 is fully inserted into the hole 25, its head 32 comes to rest and wedge against at least a portion of the edge 25_2, even if its axis 31 is inclined in relation to the axis 25_1 of the hole.

[0028] For anatomical reasons, the angle δ is advantageously chosen to be less than 45°. In the example considered in the Figures, this angle is approximately 20°.

[0029] On its outer longitudinal side 10B, the plate body 10 is chamfered, as shown in Figure 7. The corresponding generally flat chamfer 17 is oriented upwardly in the configuration of implantation of the plate 1. In this way, when the plate is implanted, the risk of the plate interfering with or even significantly pressing the extensor tendon of the metatarsal-phalangeal joint is limited.

[0030] One method for placing the arthrodesis plate 1 is as follows. After incising and clearing the soft tissue surrounding the joint to be locked, the surgeon partially resects the M_1 metatarsal and P_1 phalangeal epiphyses in order to remove bony irregularities, such as bulges from osteoarthritis, that might be present in the joint.

[0031] After having selected the plate 1 whose size is the most appropriate for the operated patient from among the set of several homothetic arthrodesis plates, the surgeon then places the plate on the M and P bones: the plate body 10 is placed on the upper surfaces of these bones, while the end 22 of the leg 20 is placed against the inner lateral surface of the phalangeal epiphysis P_1 – that is to say, in anatomical terms, its medial surface. The plate body 10 is then partially immobilized using the oblong hole 16: the surgeon inserts a screw 2 (Fig. 1) into the hole 16, on the side of the rear bottom 16_2 of this hole, without tightening the screw head against the edge of the hole. In this way, the plate body 10 remains displaceable in the direction 11 relative to the metatarsal M.

[0032] The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above. The screwing of the screw 30 is continued until the head 32 of this screw abuts, along its axis 31, against the edge 25_2 of the hole 25. As

the screw 30 continues to be screwed in, it brings the metatarsal M closer to the phalanx P, with this movement being guided along the direction 11 by the cooperation of the oblong hole 16 and the loose screw 2. The front bottom 16_1 of the hole 16 then progresses backwards in relation to the screw 2, which then progressively becomes located on the side of this front bottom 16_1. The surgeon thus continues to screw in the screw 30 until the epiphyseal ends M_1 and P_1 of the bones are substantially joined. It can be understood that the direction in which the screw 30 is inserted into the hole 25 determines the relative position of the metatarsal and the phalanx when they are fused.

[0033] The screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2.

[0034] Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.

[0035] Finally, the surgeon closes the incision.

[0036] In actual practice, the surgeon has arthrodesis plates for the metatarsal-phalangeal joint of the right foot: these plates have a structure symmetrical to that of plate 1 in relation to a vertical plane median to the latter.

[0037] Advantageously, in order to facilitate the choice of the size of the plate to be implanted, the surgeon also has a set of arthrodesis plate phantom lines at his disposal: each phantom line has external contours identical to those of one of the arthrodesis plates available in the set at his disposal so that the surgeon, after having incised the patient and performed initial bone resections, places one of these phantom lines, on the one hand, in order to select the most appropriate implant size and, on the other hand, to ensure that the resections are sufficient, particularly at the level of the coaptation zone between plate on the one hand and metatarsal and phalanx on the other hand.

[0038] Furthermore, the surgeon can, when placing the plate 1, advantageously modify the angle α in order to adjust this angle as closely as possible to the anatomical angle of dorsi-

flexion between the metatarsal M and the phalanx P of the patient being operated on, taking into account, in particular, the bone resections and the general morphology of the patient's bones, as well as his or her footwear habits and, more particularly, the height of the shoe heel.

[0039] The plate 1 is manufactured from a flat metal plate. This plate is, in a first step, cut in accordance with predetermined contours in order to secure the metatarsal 12 and phalangeal 13 parts, as well as the leg 20. The various holes 15_1 to 15_4 and the oblong hole 16 are drilled in a second step. In a third step, sections 12_1 and 13_1 are bent while the plate is folded along lines 12_3, 13_3, 23 and 24.

[0040] Various arrangements and variants of the above-described plate 1 and its method of installation are conceivable. For example:

- The underside of the plate is blasted or, more generally, undergoes a surface treatment in order to promote bone colonization once the plate is implanted; and/or:

- The number of holes 15_1 through 15_4 may be varied, particularly depending on the longitudinal size of the plate body 10.

Claims

1. Arthrodesis plate (1) for a metatarsophalangeal joint, comprising an elongated plate body (10) adapted to be put in place and fixed on the respective top faces of the metatarsal (M) and phalange (P) connected by the joint to be locked by arthrodesis so as to extend lengthwise straddling the joint,
characterised in that the plate body (10) is fitted with an elongated leg (20) for fixing to a lateral face of the epiphysis (P_1) of the phalange (P), which leg extends lengthwise from a longitudinal side (10A) of the plate body and at the longitudinal end (22) opposite the plate body is provided with a through hole (25) adapted to take an elongated means (30) of osseous anchorage in the phalange (P) and metatarsal (M) at the same time, such as a long screw.

2. Plate according to claim 1, **characterised in that** according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, the leg (20) extends in a longitudinal direction (21), which forms an angle (β) of between 20 and 60°, preferably equal to 40° +/-1°, with the longitudinal direction (11) of the plate body (10).

3. Plate according to one of claims 1 or 2, **characterised in that** the through hole (25) of the leg (20) is adapted to take the means of osseous anchorage (30) in a position, in which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, the longitudinal direction (31) of this means of anchorage, such as the central shaft of a long screw, forms an angle (δ) of less than 45° with the longitudinal direction (11) of the plate body (10).

4. Plate according to any one of the previous claims, **characterised in that** the leg (20) is folded according to at least one folding line (23, 24) more or less perpendicular to the longitudinal direction (21) of the leg.

5. Plate according to any one of the previous claims, **characterised in that** along its length the plate body (10) comprises a metatarsal part (12) and a phalangeal part (13), adapted to be put in place and fixed on the top faces of the metatarsal (M) and phalange (P) respectively, and **in that** the leg (20) extends from the phalangeal part (13), preferably forming a solid block with it.

6. Plate according to claim 5, **characterised in that**

the metatarsal part (12) is provided with an oblong through hole (16), the longitudinal direction of which is more or less parallel to the longitudinal direction (11) of the plate body (10).

7. Plate according to one of claims 5 or 6, **characterised in that** the metatarsal part (12) includes on the one hand, on the same longitudinal side (10A) of the plate body (10) as the leg (20), an arched section (12_1), the concave face (12_{1A}) of which is adapted to come into contact and surround the top convex face of the metatarsal diaphysis (M_2), and on the other hand a more or less flat section (12_2) connecting the arched section to the phalangeal part (13).

8. Plate according to claim 7, **characterised in that** the arched section (12_1) and the more or less flat section (12_2) of the metatarsal part (12) are folded in relation to each other according to a folding line (12_3), which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, forms an angle (γ_M) of between 10 and 20° with the longitudinal direction (11) of the plate body (10), homothetical values of this angle preferably being provided between the limits of 12° and 18° for a set of arthrodesis plates of different respective sizes.

9. Plate according to any one of claims 5 to 8, **characterised in that** the phalangeal part (13) includes on the one hand, on the same longitudinal side (10A) of the plate body (10) as the leg (20), an arched section (13_1), the concave face (13_{1A}) of which is adapted to come into contact and surround the top convex face of the phalange diaphysis (P_2), and on the other hand a more or less flat section (13_2) connecting the arched section to the metatarsal part (12).

10. Plate according to claim 9, **characterised in that** the arched section (13_1) and the more or less flat section (13_2) of the phalangeal part (13) are folded in relation to each other according to a folding line (13_3), which according to a more or less vertical direction of observation (arrow II), when the plate (1) is implanted, forms an angle (γ_P) of between 15 and 25°, preferably equal to 20° +/-1°, with the longitudinal direction (11) of the plate body (10).

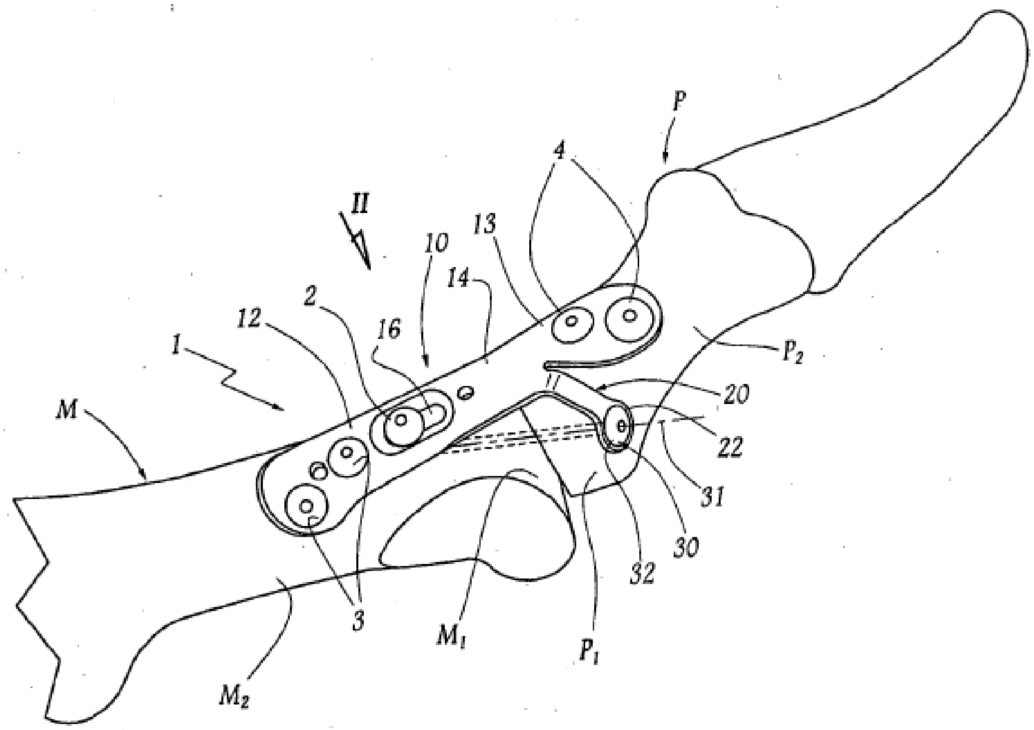
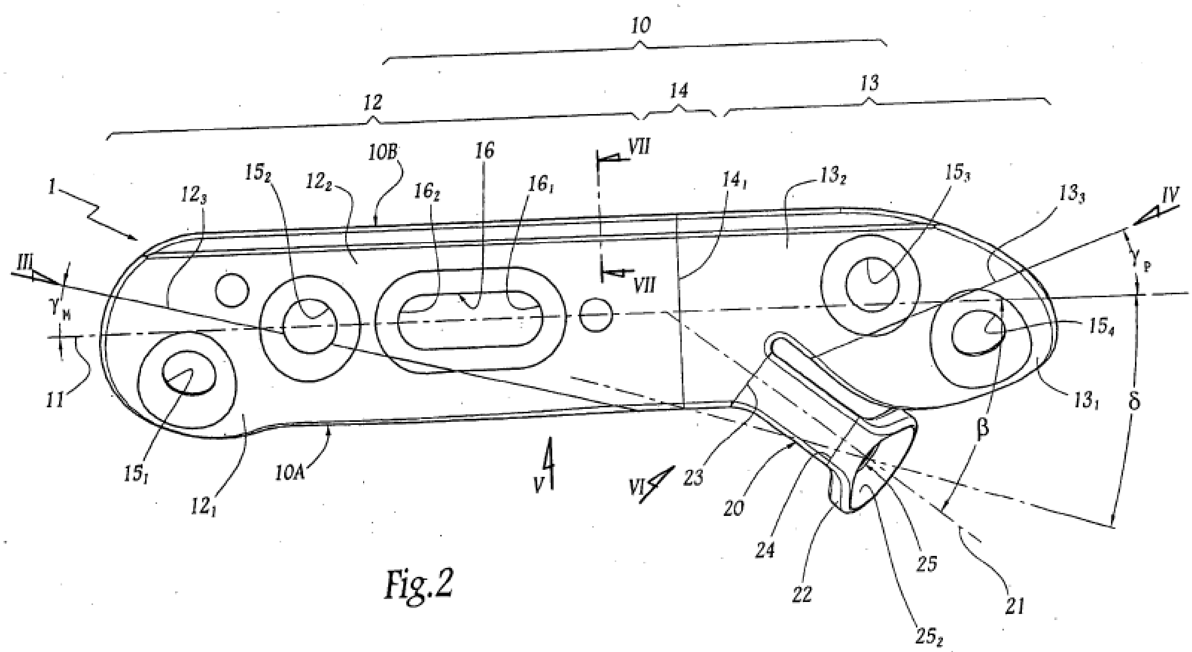


Fig. 1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13_3
IV
III
γ_M
γ_P
VII
15_4
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β
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12_1
V
VI
23
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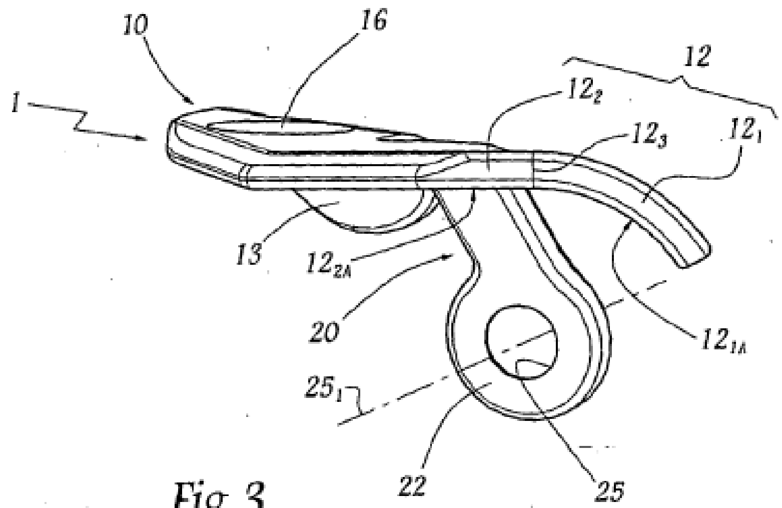
22
25
21
25_2

Fig.2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12_{2A}
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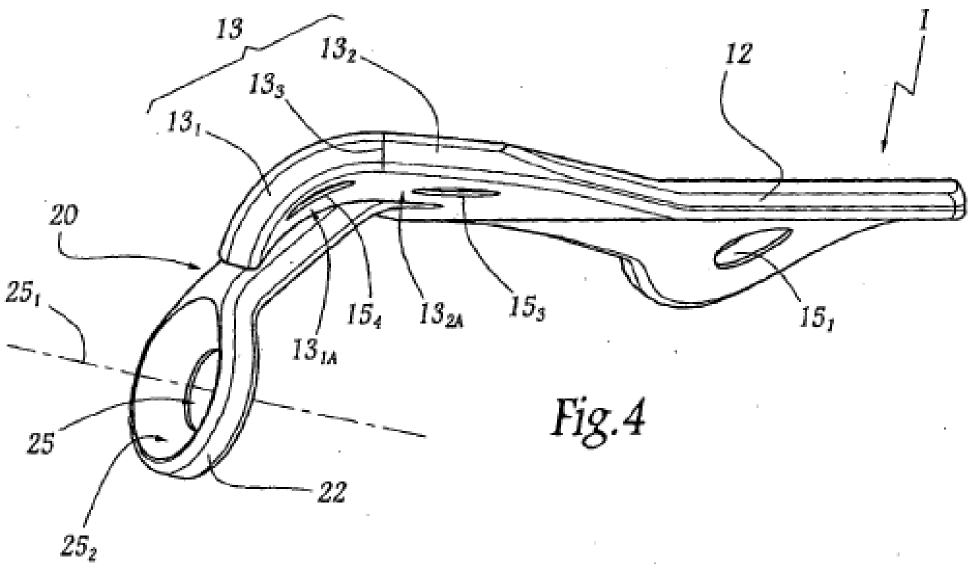
12_{1A}
25_1
22
25

Fig.3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25_2

Fig.4

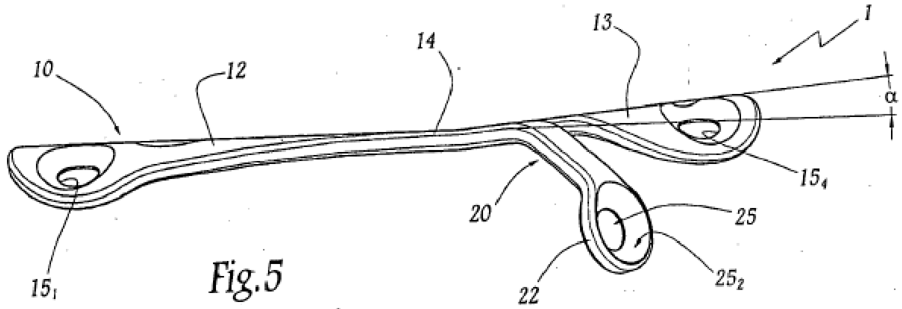

Fig.5

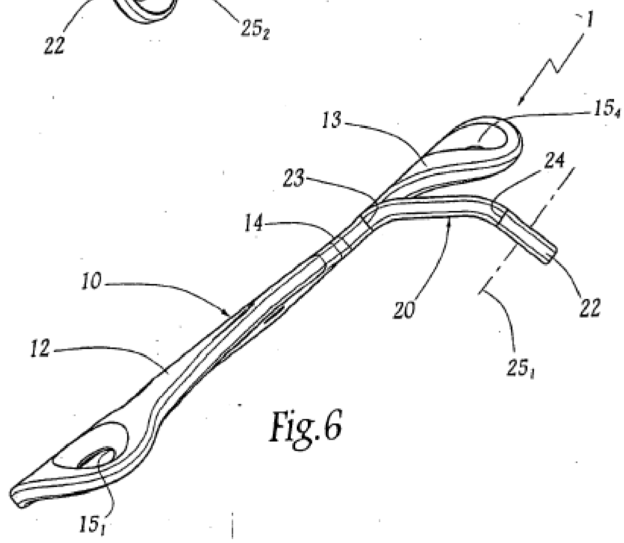

Fig.6

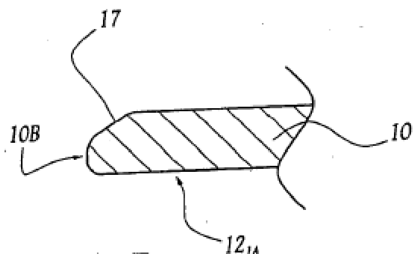

Fig.7

EP 1 897 509 B1

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This list of references cited by the applicant is intended only to assist the reader and does not form part of the European patent document. Although great care has been taken in its preparation, errors or omissions cannot be excluded and the EPO accepts no liability in this regard.

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BURG
TRANSLATIONS

134 N. LaSalle St.
Suite 1550
Chicago IL 60602
USA
800 959 2874

May 27, 2021

I, **Erin Stansifer,** having been duly sworn, depose and say that the translations into **English** of the following documents:

- **Arnauld EP1897509B1_English**
- **Arnauld FR2905590A1_English**

have been translated by Burg Translations, Inc. and, to the best of my knowledge and belief, they are true and accurate rendering of the original **French** documents.

STATE OF ILLINOIS, COUNTY OF COOK
Chicago, Illinois, May 27, 2021
Subscribed and sworn before me on this 27th day of May, 2021

Erin Stansifer

Erin Stansifer

ANGELO PASSALACQUA
Official Seal
Notary Public - State of Illinois
My Commission Expires Nov 29, 2024

Angelo Passalacqua, Notary Public

US008187276B1

(12) **United States Patent**
Zahiri et al.

(10) **Patent No.: US 8,187,276 B1**
(45) **Date of Patent: May 29, 2012**

(54) **ODD ANGLE INTERNAL BONE FIXATION DEVICE FOR USE IN A TRANSVERSE FRACTURE OF A HUMERUS**

(76) Inventors: **Christopher A. Zahiri**, Los Angeles, CA (US); **Hormoz Zahiri**, Los Angeles, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 782 days.

(21) Appl. No.: **11/527,927**

(22) Filed: **Sep. 26, 2006**

(51) **Int. Cl.**
A61B 17/76 (2006.01)

(52) **U.S. Cl.** **606/65**

(58) **Field of Classification Search** 606/65–68, 606/53, 280–289, 297, 62, 71, 105, 70, 63, 606/64; 403/362
See application file for complete search history.

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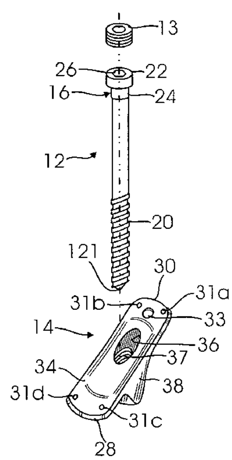
Primary Examiner — Eduardo C Robert
Assistant Examiner — Jerry Cumberledge
(74) *Attorney, Agent, or Firm* — Thomas I. Rozsa

(57) **ABSTRACT**

The present invention is an improved unique odd angle internal fixation device for both a transverse and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus. The improved odd angle internal fixation device includes an elongated lag screw and a rectangular shaped guide plate having multiple holes throughout the plate to host pins and screws and four tips on the front side of the plate. A lag screw with a cylindric head having a hexagonal cavity introduced through the diaphyseal segment of the fracture at three angles, 90, and 150 and 160 degrees, cross fixing the respective bone longitudinal and transverse fracture line and settling in the depth of the epiphysis. An additional locking screw is introduced on the top of the lag screw head to securely lock the lag screw after being settled into the epiphysis. The guide plate serves as a guide for the lag screw and allows the engagement of the head of the lag screw to the inner wall of its short barrel portion. The engagement would cause the guide plate which is attached to the barrel, to be compressed against the diaphyseal cortex as the lag screw advances deeper into the epiphysis at said three angles.

21 Claims, 5 Drawing Sheets



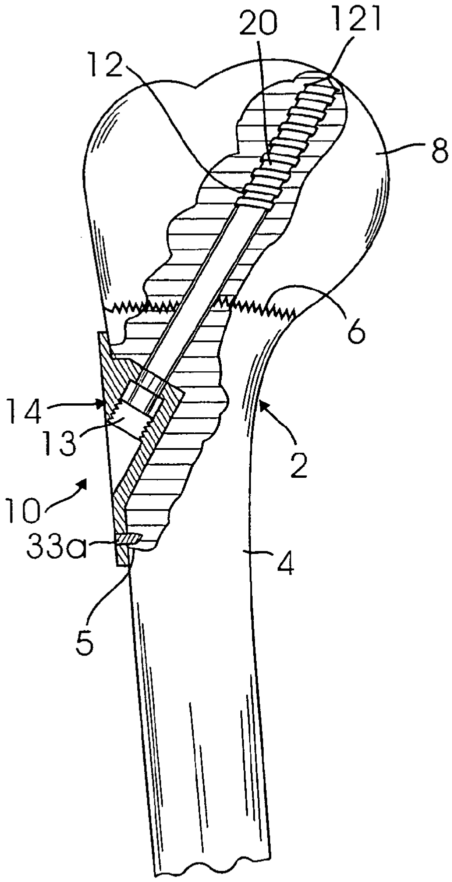

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Fig. 1

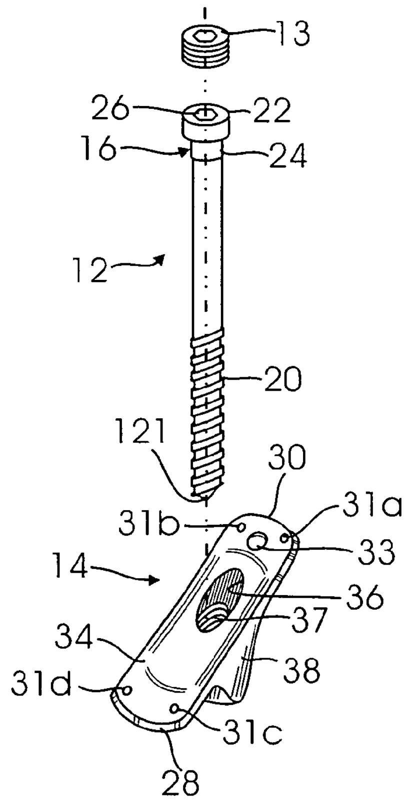
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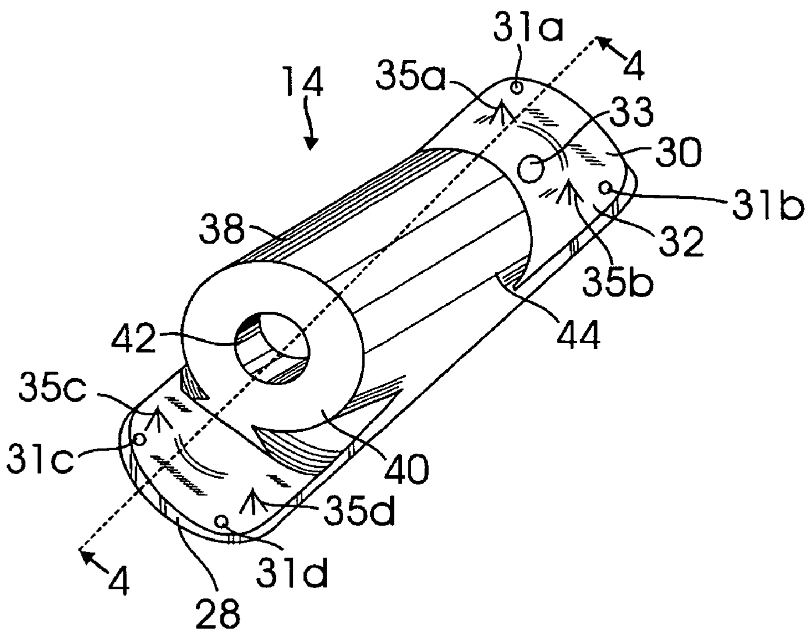
Fig. 2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31d
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Fig. 3

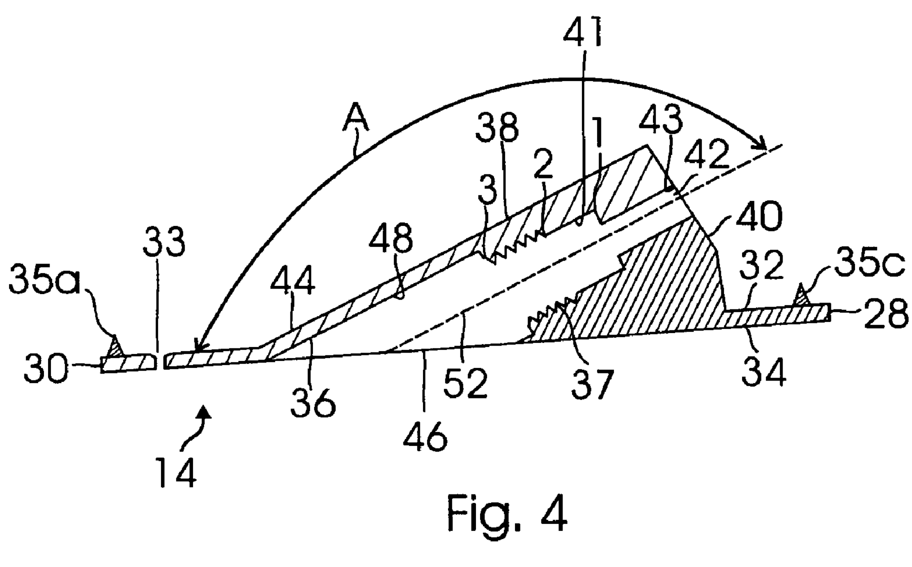
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Fig. 4

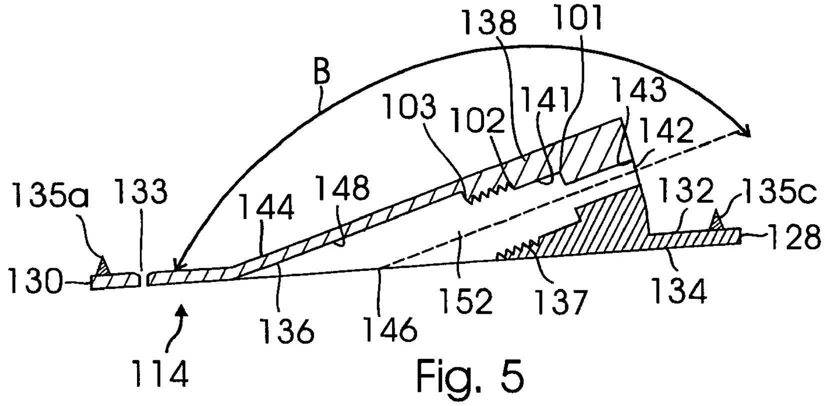

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Fig. 5

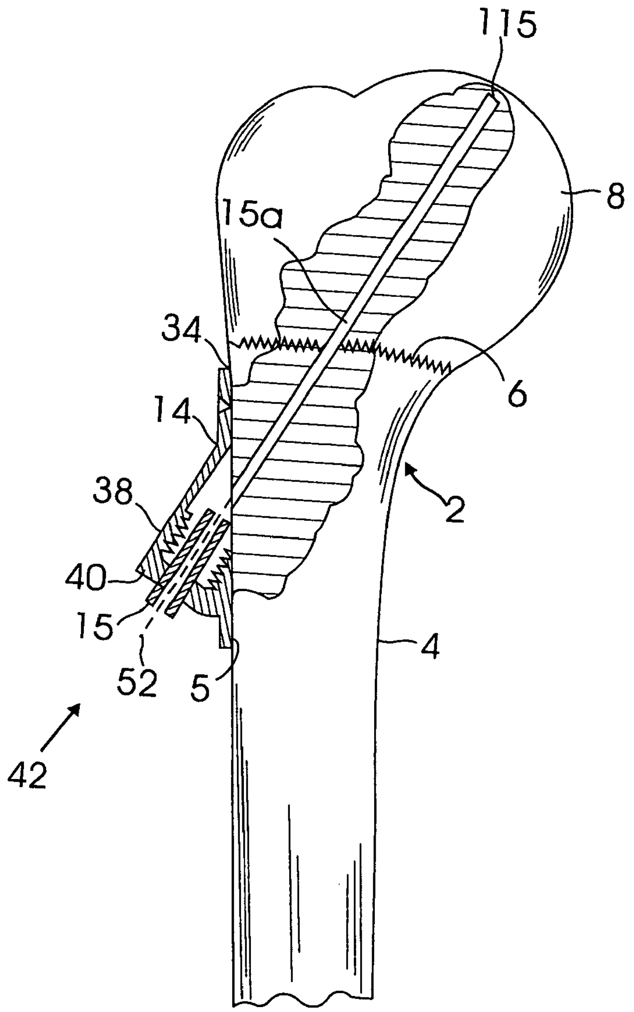

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Fig. 6

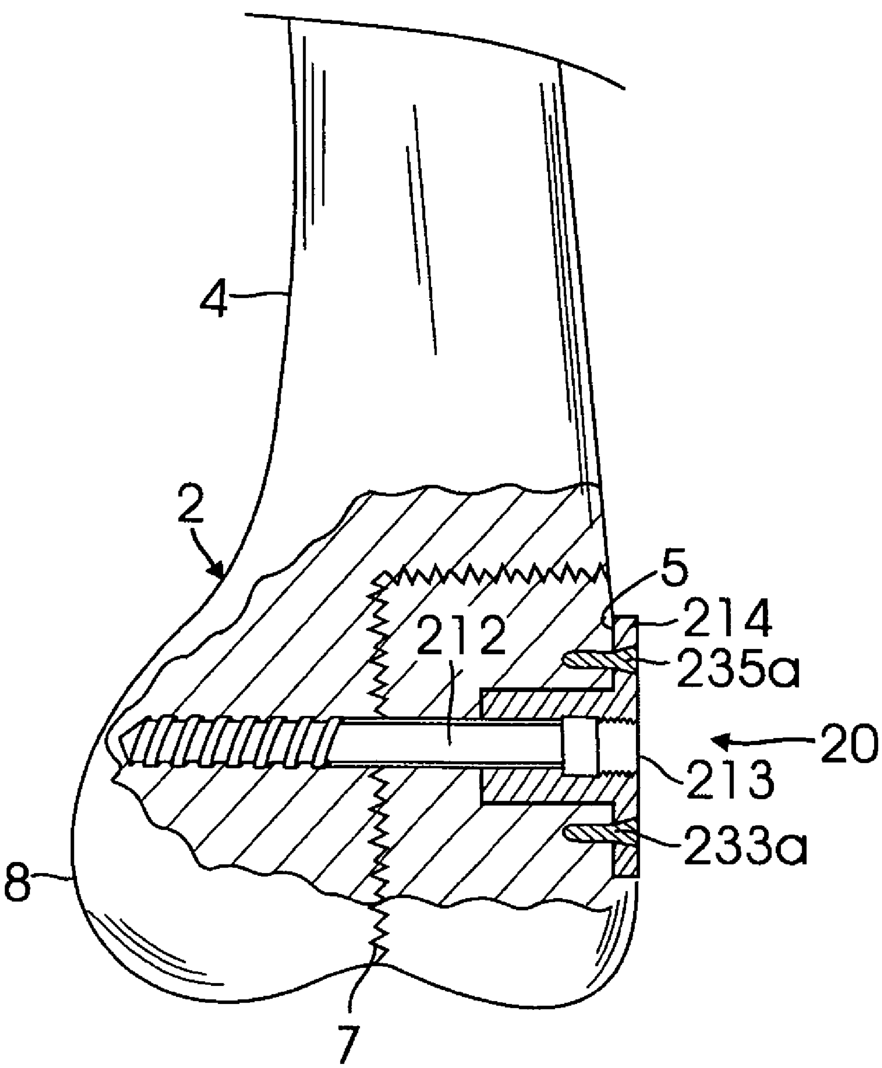

Fig. 7

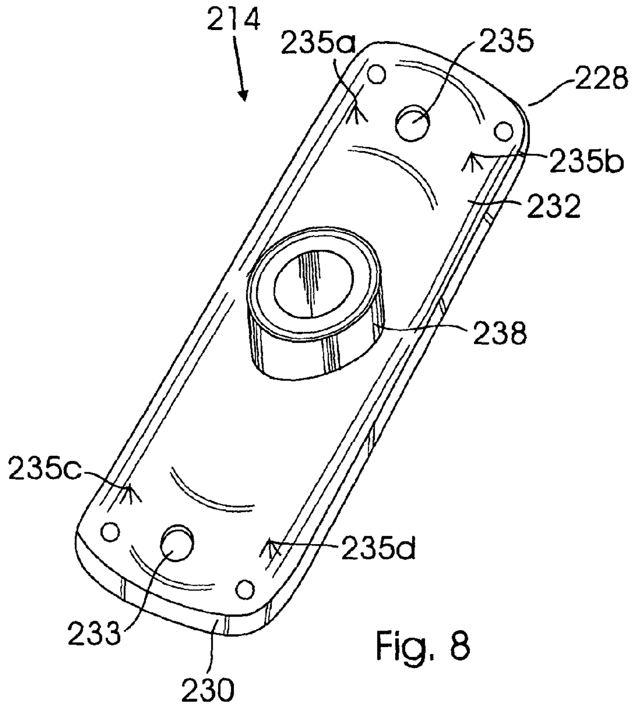
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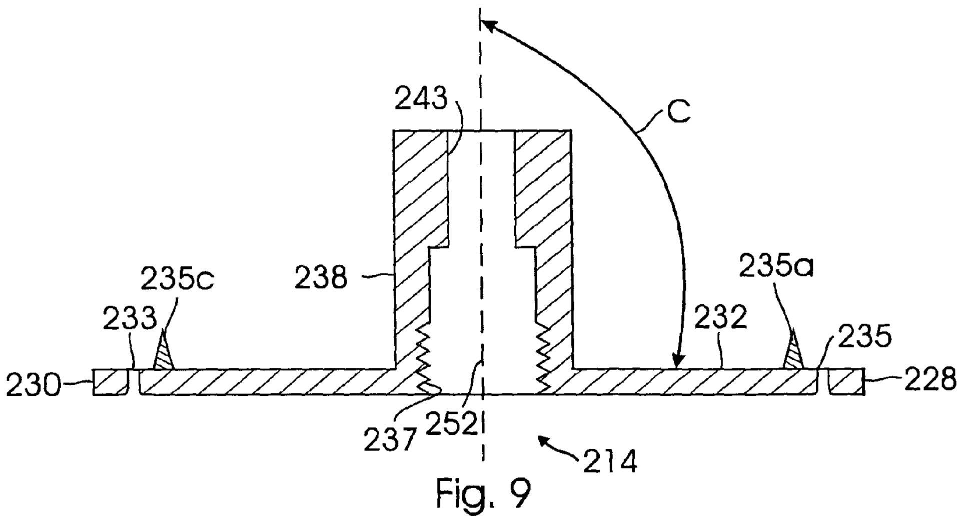
Fig. 8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252
214

Fig. 9

ODD ANGLE INTERNAL BONE FIXATION DEVICE FOR USE IN A TRANSVERSE FRACTURE OF A HUMERUS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of medical devices. More particularly, the present invention relates to the field of fixation devices for compressing bone fractures of a human being.

2. Description of the Prior Art

U.S. Pat. No. 5,693,055 by the same inventors discloses a unique odd angle internal fixation device for a transverse fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus. The device includes an elongated lag screw and a rectangular shaped guide plate. The lag screw is introduced through the diaphyseal segment of the fracture at an angle ranging approximately between 155° to 170°, cross fixing the bone fracture line and settling in the depth of the epiphysis. The guide plate serves as a guide for the lag screw and allows the engagement of the head of the lag screw to the inner wall of its short barrel portion. The engagement causes the guide plate which is attached to the barrel to be compressed against the diaphyseal cortex as the lag screw advances deeper into the epiphysis at an angle ranging approximately between 155 degrees to 170 degrees. The device provided with a lag screw and a guide plate which has an inclined short barrel portion integrally attached to the guide plate at an angle from above said range will cross fix a fracture line of the junction of the metaphysis and diaphysis, or cross fix the osteotomy site of the junction of the metaphysis and diaphysis or it can be used for joint fusion.

It will be appreciated that the U.S. Patent discloses the device which has a correct mechanism for fixing the bone transverse fracture. However it must also be appreciated that there are a number of areas where the structure of the device could be improved so as to fix both longitudinal and transverse fractures.

This prior art odd angle internal bone fixation device with the screw having a slotted top end from its proximal head does not create a user friendly condition for a surgeon. This is because surgeon can only tighten the lag screw when the position of the flat head of a screw driver used by the surgeon matches the position of the slotted top end of the lag screw. Therefore, the surgeon must redirect part of his attention to the position of the screw driver he is using, which could create problems if the surgeon must divert his attention from the medical issues of the surgical operation.

In addition, this prior art rectangular shaped guide plate of the device also does not create a user friendly condition for the surgeon since it is difficult for the surgeon to stabilize the plate at a position of the diaphsis cortex of the humerus determined by the surgeon, and in addition the plate is unstable in operation when the lag screw is pushed and turned to settle into the bone. An appropriate structural fixture designed for the plate is necessary to make it easily lock at a position of the diaphsis cortex and further keep it stable during operation when the lag screw is pushed and turned into the bone structure.

Another problem with the prior art device is that the screw which settles in the depth of the epiphysis after surgery could be loosened from its initial position if a patient performs excess movement of the body part where the fractured bone is located. To avoid such risk, the patient is advised to have a limited movement of the body part until the screw is fussed with the born structure, which could take a long time to happen. Obviously, this creates potential problems for the patient.

In addition, it is difficult for the surgeon to precisely follow a desired angle for driving the lag screw to settle into the bone without having a guide hole with the desired angle through a path that the lag screw is intended to drive through.

There is a significant need for a device which can be used to fix a longitudinal bone fracture in addition to its application to fix a transverse bone fracture, since longitudinal bone fractures also frequently occur.

SUMMARY OF THE INVENTION

The present invention is an improved unique odd angle internal fixation device for both a transverse and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus.

The improved odd angle internal fixation device includes an elongated lag screw and a rectangular shaped guide plate having multiple holes throughout the plate to host pins and screws and four tips on the front side of the plate. A lag screw with a cylindrical head having a hexagonal cavity is introduced through the diaphyseal segment of the fracture at three angles, 90 degrees, and 150 degrees or 160 degrees, cross fixing the respective bone longitudinal and transverse fracture line and settling in the depth of the epiphysis. An additional locking screw is introduced on the top of the lag screw head to securely lock the lag screw after being settled into the epiphysis. The guide plate serves as a guide for the lag screw and allows the engagement of the head of the lag screw with the inner wall of its short barrel portion. The engagement would cause the guide plate which is attached to the barrel to be compressed against the diaphyseal cortex as the lag screw advances deeper into the epiphysis at said three angles.

The improved odd angle internal fixation device further contains newly designed four pins and one or two additional screws through the plate as well as four tips on the front side of the guide plate. The pins are used to aid ib locating the plate at a position of the diaphsis cortex of the humerus, and are also used to stabilize the plate during a surgical operation when the lag screw is pressed and turned into the humerus. The pins are removed after the lag screw is settled inside of the epiphysis. The screws provide additional force to compress the plate to the cortex of the humerus in addition to the lag screw which provides a predominant contribution for compression of the plate. The four tips are also able to lock in the plate when they are pressed into the bone cortex after the lag screw is engaged into the depth of the epiphysis. The guide plate is further designed to be able to aid in making a guide hole at a desired angle so that the lag screw can be turned into the bone at the desired angle following the guide hole.

It has been discovered, according to the present invention, that if an odd angle internal fixation device is provided with a lag screw and a guide plate which has an inclined short barrel portion integrally attached to the guide plate at a degree angle of 150 degrees, or 160 degrees, then it will cross fix a transverse fracture line of the junction of the metaphysis and diaphysis, or cross fix the osteotomy site of the junction of the metaphysis and diaphysis or it can be used for joint fusion. With the addition of a 90 degree angle screw, it will cross fix a longitudinal fracture line located in the epiphysis portion of the bone.

It has further been discovered, according to the present invention, that if the lag screw has the hexagonal cavity on its

top head, it will prove a user friendly condition to the surgeon to tighten the lag screw into the epiphysis during a surgical procedure.

It has also been discovered, according to the present invention, that if an additional locking screw is introduced on the top of the lag screw after it has settled inside of the epiphysis to securely lock the lag screw, it will provide stability of the lag screw inside of the bone immediately after a surgical operation even if there is excess movement of the body part where the fractured bone is located.

It has also further been discovered, according to the present invention, that the plate of the device can be prefixed on the cortex of the bone if additional pins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.

It has been discovered, according to the present invention, that one or two additional screws can be added into the plate, which will enhance tight contact from the plate to the cortex of the bone after the screws are turned into the bone structure. The plate will be further stabilized if tips are designed on the front side of the plate, which lock in the plate on the cortex after the plate is pressed to locate on the cortex of the bone.

It has additionally been discovered, according to the present invention, that with the aid of a newly designed hollow cylinder placed inside of the barrel of the guide plate, the guide plate can be further used to help make a guide hole on the bone for guiding the lag screw precisely to settle into the bone at a desired angle.

It is therefore an object of the present invention to provide an improved odd angle internal fixation device which can cross fix a transverse, or a longitudinal fracture line, osteotomy site or joint fusion at a respective angle of 150 degrees and 160 degrees, or 90 degrees.

It is a further object of the present invention to design a hexagonal cavity of the head of the lag screw to provide the surgeon with a user friendly condition to tight the screw into the epiphysis.

It is an additional object of the present invention to provide a guide plate which has additional fixation pins, screws, and tips which are specifically used to stabilize the guide plate against the bone cortex at a position for a surgical process before, during, and after the surgical operation when the lag screw is driven into the epiphysis.

It is an further additional object of the present invention to provide a locking screw on the top of the lag screw settled inside of the bone to stabilize the position of the lag screw immediately after surgery even in a situation where there is excess movement of the body part where the fractured bone is located.

It is an additional object of the present invention to provide a hollow cylindrical accessory, which can be placed inside of the barrel of the guide plate, so that the plate can be used to help make a guide hole at a desired angle for the lag screw wherein the lag screw can be driven along the guide hole to be precisely settled inside of the bone.

In the preferred embodiment of the present invention, a major point of uniqueness is having the odd angle internal fixation device which includes an elongated lag screw and a rectangular shaped guide plate which has a short barrel portion at an inclined angle of 90 degrees, 150 degrees, and 160 degrees. However, it should be appreciated that the present invention can also be utilized with a rectangular shaped guide plate which has a short barrel portion at an inclined angle in the range of from 90 to 170 degrees.

Further novel features and other objects of the present invention will become apparent from the following detailed description, discussion and the appended claims, taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring particularly to the drawings for the purpose of illustration only and not limitation, there is illustrated:

FIG. **1** is a side elevational view in partial cross-section of one of the embodiments of the present invention improved odd angle internal fixation device, showing the device fitted at two preferred angles of 150 degrees and 160 degrees to fix a transverse fracture, as it would be used, with portions of the diaphysis being cut away for illustrative purposes;

FIG. **2** is an enlarged exploded perspective view the present invention improved odd angle internal fixation device, shown in the embodiment of FIG. **1**;

FIG. **3** is an enlarged top perspective view of the rectangular shaped guide plate with a guide angle of 150 degrees or 160 degrees;

FIG. **4** is a cross-sectional view taken along line **4-4** of FIG. **3**, showing the short barrel portion of the guide plate at an angle of 150 degrees;

FIG. **5** is a cross-sectional view of another embodiment of the present invention rectangular shaped guide plate, showing the short barrel portion at an angle of 160 degrees;

FIG. **6** is a side elevational view in partial cross-section to illustrate the plate with the access used for helping to draw a guide hole;

FIG. **7** is a side elevational view in partial cross-section side elevational view of another one of the embodiments of the present invention improved odd angle internal fixation device, showing the device fitted at 90 degree to fix a longitudinal fracture, as it would be used, with portions of the diaphysis being cut away for illustrative purposes;

FIG. **8** is a top perspective view of the front surface of the rectangular shaped guide plate having a 90 degree angle shown in FIG. **6**; and

FIG. **9** is a cross-sectional view of still another embodiment of the present invention rectangular shaped guide plate, showing the short barrel portion at an angle of 90 degrees.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Although specific embodiments of the present invention will now be described with reference to the drawings, it should be understood that such embodiments are by way of example only and merely illustrative of but a small number of the many possible specific embodiments which can represent applications of the principles of the present invention. Various changes and modifications obvious to one skilled in the art to which the present invention pertains are deemed to be within the spirit, scope and contemplation of the present invention as further defined in the appended claims.

Referring to FIG. **1**, there is shown at **10** one of the embodiments of the present invention improved odd angle internal fixation device, illustrating the device fitted as it would be used in a fracture of the diaphysis **2**. The improved odd angle internal fixation device **10** includes an elongated lag screw **12**, a plate **14**, a locking screw **13**, and an additional screw **33***a* introduced through the diaphyseal segment **4** of the fracture at an angle of 150 degrees or 170 degrees, cross fixing the transverse fracture line **6** and settling in the depth of the epiphysis **8**.

FIG. **2** shows an enlarged exploded perspective view of the present invention improved odd angle internal fixation device **10** which includes the locking screw **13**, the elongated lag screw **12** and the generally rectangular shaped guide plate **14**. Referring to FIGS. **1** and **2**, the lag screw **12** has a proximal portion **16** and a distal threaded portion **20** with an end **121**. The proximal portion **16** is provided with a proximal head **22** and a proximal cylinder **24**. The proximal head **22** has a hexagonal cavity **26** which is provided to accommodate a driving tool, such as a hexagonal tip screwdriver to drive the lag screw **12** into the epiphysis **8**. With the improvement applying the hexagonal structure, the present invention provides the surgeon a user friendly condition for driving the lag screw, so that the surgeon does not need to pay attention as to whether or not the position of the flat head of the screw driver matches that of the slotted top end of the lag screw disclosed in the prior U.S. Pat. No. 5,693,055. Therefore, the doctor can fully concentrate on the medical details of the surgical operation. This improvement is significant since it eliminates an interference factor to the surgeon during a surgical operation and enhances the assurance of the success of the surgery.

It will be appreciated that the cavity **26** is not limited to the hexagonal shape. The proximal head **22** can be manufactured with a cross head top end, so that a cross-headed screwdriver can drive the lag screw **12** into the diaphysis.

The lag screw **12** has different diameters. The diameter of the proximal cylinder **24** is the smallest diameter and is the same as the diameter of the thread depth of the distal threaded portion **20**. The diameter of the proximal head **22** is the largest, which is larger than the diameter of the threads of the distal threaded portion **20**.

FIG. **3** shows an enlarged top perspective view of the rectangular shaped guide plate **14**. FIG. **4** shows a cross-sectional view of the guide plate **14**. Referring to FIGS. **2**, **3** and **4**, the guide plate **14** has two opposite ends **28** and **30**, a front side **32**, a back side **34**, and a bore **36**, which contains a threaded portion **37** therethrough which is located off-center and adjacent to one end **30** of the guide plate **14**. The two opposite ends **28** and **30** are generally linear with two round corner at both ends. The plate **14** is slightly curved on its transverse ends. As shown in FIG. **2**, there is illustrated a convex backside **34** of the plate **14**. As also shown in FIG. **3**, the front side of the plate **14** is concave. With the aid of the curved structure, the plate **14** is able to better fit the diaphseal segment of the humerus when the front side **32** of the plate is pressed to contact the cortex **5** shown in FIG. **1**.

Referring to FIGS. **2** and **3**, there is illustrated the guide plate **14** having four small holes **31***a*, **31***b*, **31***c*, and **31***d* respectively located at each corner of the rectangular plate and a medium size hole **33** located on the cental line of the plate close to the proximal end **44**. All of the five holes are perpendicular through the plate. The plate further has four tips **35***a*, **35***b*, **35***c*, and **35***d* also respectively located close to each corner of the plate **14**, but they are further away from the corners than the four small holes. The four tips are arranged perpendicular to the plane, wherein they extend from the back side **34** to the front side **32** of the plate **14**. These four tips also serve to lock the plate when the plate is pressed to the diaphsis cortex of the humerus. It will be appreciated that these four tips could be located at other places on the front surface of the plate. It will further be appreciated that more or less tips could be used as long as they are able to lock the plate on the cortex. The hole **33** is designed to host an additional screw **33***a* to fix the plate **14** to the diaphsis cortex of the humerus.

The present invention improved odd angle internal bone fixation device provides a guide plate which is transversely curved, and can dissipate all the compression forces of the odd angle internal fixation device that are applied against the bone cortex, and practically reduce the forces to an easily tolerable level by the bone cortex. The repetitive normal use of the upper extremity after fixation cannot cause any failure by loosening of the device because the forces applied are well dissipated around the guide plate, and therefore the bone cortex remains healthy and intact. The guide plate is designed to serve as a very low profile fixation device palpable over the patient's extremity at the surgical site. The guide plate is far less prominent than the head of a screw, especially when used at an angle.

Referring to FIGS. **3** and **4**, there is shown a short barrel portion **38** which is integrally attached to the guide plate **14**. The short barrel portion **38** is a cylindrical hollow structure, having a distal end **40** with an opening **42**, an opening side wall **43**, an inner cylindrical wall **41**, a threaded side wall portion **37**, an inner side wall **48**, and a proximal end **44** with an opposite opening **46**. Further referring to FIG. **4**, there is illustrated the threaded wall portion **37** which has a length defined between the second point **2** to a third point **3**, which is slightly less than the height of the locking screw **13**. The inner cylinder wall **41** has a length defined between the first point **1** and the second point **2**, which is the same as the height of the proximal head **22** of the lag screw **12**. The opening side wall **43** connected to the threaded wall **37** connected to the inner side wall **48** defines a passage **52** which extends from the distal end opening **42** to the proximal end opening **46**, where the internal diameter of the opening side wall **43** is the least smallest, the inner side wall **48** the largest diameter, and the threaded wall **37** has the intermediate diameter. The proximal end **44** of the short barrel portion **38** is integrally attached to the front side **32** of the guide plate **14** at an inclined angle "A" of 150 degrees such that the proximal end opening **46** of the barrel portion **38** communicates with the bore **36** of the guide plate **14**.

Referring to FIGS. **6**, **2** and **4**, the operation of the present invention improved odd angle internal fixation device **10** will be described. Before a surgical operation, an X-Ray analysis is performed, which determines a point in the longitudinal portion of the diaphyseal segment wherein a guide hole is going to be drilled, an angle of 140 degrees or 160 degrees is appropriate starting from the point, and extending for a distance from the point along the appropriate angle to cross the transverse fracture. After reading the results of the X-Ray analysis, the surgeon selects the improved odd angle internal bone fixation device wherein the guide plate contains the desired angle, and the lag screw has an appropriate length that is sufficient to cross the fracture line.

Referring to FIG. **6**, there is illustrated a procedure to make a guide hole for the lag screw **12**. In the procedure, the guide plate **14** is first placed at a location on the cortex, wherein the passage **52** is positioned at the point predetermined by x-Ray analysis. The plate **14** is further positioned so that its central longitudinal line is along to the longitudinal direction of the diaphyseal segment of the bone and the backside **34** of the plate **14** contacts the bone cortex. A drawing guide **15** is then slidably inserted into the passage **52** of the short barrel **38** from the opening **42** at the distal end **40** of the barrel **38**, wherein the drawing guide **15** is a hollow cylinder having a central hole around its cylindrical rotational axis. The drawing guide **15** has a outside diameter which is slightly less than that of the opening **42**. Referring to FIG. **6**, the length of the drilling guide **15** is longer that of the barrel **38**. Therefore, the drilling guide **15** has the same angle as that of the barrel **38** aligned against the diaphsis cortex of the humerus. Then a long drill shaft from a conventional drill is inserted into the hole of the drilling guide **15**, wherein the diameter of the drill

bit is sufficiently less than that of the hole, and a guide hole **15***a* is drilled following the desired angle wherein the end **115** of the hole **15***a* passes through the fracture line **6**. After completion of the guide hole **15***a*, the guide plate **14** is removed. An additional hole with an appropriate diameter is then drew starting at the opening of the guide hole on the cortex following the direction of the desired angle and ending at a position, wherein the newly created hole can host the barrel **38** portion of the guide plate **14**. The end point of the hole to host the barrel portion determines a new opening **215** (not show) of the guide hole **15***a*, along the direction of the desired angle.

Referring to FIGS. **1**, **2**, **4**, and **6**, the operation of the present invention improved odd angle internal fixation device **10** will be described. The short barrel portion **38** of the guide plate **14** is positioned within the hole formed through above described operation, wherein four tips **35***a*, **35***b*, **35***c*, and **35***d* on the front side **32** contact the diaphsis cortex of the humerus. Four small holes with their size less than the diameter of hole **31***a*, **31***b*, **31***c*, and **31***d* are drilled into the cortex. Then four pins are pressed throughout the hole **31***a*, **31***b*, **31***c*, and **31***d* in a direction from the back side **34** to the front side **32** of the plate **14** and pushed partially into the bone to lock the guide plate **14**. The lag screw **12** is then slidably received within the passage **52** of the barrel portion **38** from the back side **34** of the guide plate **14**, where the interior of the short barrel portion **38** is designed so that the lag screw **12** engages into the barrel portion **38** at three different diameters of the passage **52**. The lag screw **12** is then threaded into the guide hole **15***a* to advance into the epiphysis **8** when its end **121** hits the opening **115** of the guide hole **15***a*. When the lag screw **12** is received within the short barrel portion **38**, the diameter of the proximal shoulder flange **24** is slightly less than the internal diameter of the distal end opening **42** of the barrel portion **38** and provides a press fitted engagement thereon. The proximal head **22** of the lag screw **14** is slightly less than the diameter of the thread surface **37** of the short barrel portion **38** and provides a press fitted engagement thereon. This would create the desired precision for the engagement and provides the necessary mechanical advantage for utmost solid compression in the improved odd angle internal fixation device **10**. In this situation, four tips on the front side **32** of the plate **14** will be pressed further into the bone cortex due to pressure force of the lag screw **12** engaged into the epiphysis **8**, which results in additional force to stabilize the plate **14** onto the bone cortex, in addition to of the pressure force provided by the lag screw **12**. It is understood that a perfect contact is reached between the concave front surface **32** of the plate **14** and the convex bone cortex in this operation.

Once the lag screw **12** is received within the barrel portion **38**, the distal threaded portion **20** extends out of the barrel portion **38** and is introduced through the diaphyseal segment **4** of the fracture at angle "A", cross fixing the fracture line **6** and settling in the depth of the epiphysis **8**.

In this operation, the specially designed guide plate **14** and the guide hole **15***a* serve to guide the elongated lag screw **12** and allow the engagement of the proximal head **22** of the lag screw **12** to the threaded wall **37** of the short barrel portion **38**. The engagement would cause the guide plate **14** which is attached to the barrel portion **38**, to be compressed against the diaphyseal cortex **5** as the lag screw **12** advances deeper into the epiphysis **8** at an angle of 150 degrees or 160 degrees.

After the lag screw **12** is settled inside of the epiphysis **8** the four pins are pulled out, and a medium size screw **33***a* is pressed and turned through the hole **33** of the plate **14** and into the bone diaphyseal segment. The screw **33***a* provides an additional force to press the guide plate **14** on the bone. After these processes, a locking screw **13** is introduced into the passage **52** of the barrel portion **38** from the opening **46** on the backside **34** of the guide plate **14**, wherein the internal diameter of the passage **52** is sufficiently lager than the diameter of the locking screw **13**. After the locking screw **13** reaches the first thread of threaded surface **37**, the locking screw **13** is then turned and threaded forward to the head **22** of the lag screw **12**. Finally the locking screw **13** is stopped when it contacts the top surface of the head **22** of the lag screw **22**, which results in a secure lock of the lag screw **12** at its residing position inside of the epiphysis shown in FIG. **1**.

Referring to FIG. **5**, there is shown a cross-sectional view of another embodiment of the present invention improved odd angle internal fixation device. The parts are numbered correspondingly with 100 added to each number. This embodiment is identical to the first embodiment as previously described in FIGS. **1** through **4** except that the short barrel portion **138** of the guide plate **114** is now at an angle "B" which is at 160°. The same elongated lag screw is used with this embodiment, and since it assembles and functions the same as previously described, and the description thereof will not be repeated.

Referring to FIG. **7**, there is shown at **20** another one of the embodiments of the present invention improved odd angle internal fixation device, illustrating the device fitted as it would be used in the longitudinal fracture of the epiphysis **8**. The improved odd angle internal fixation device **20** including an elongated lag screw **212**, a plate **214**, a locking screw **213**, and two additional screws **233***a* an **235***a* is introduced through the epiphysic segment **8** of the fracture at an angle of 90 degrees, cross fixing the longitudinal fracture line **7** and settling in the depth of the epiphysis **8**.

As illustrated FIG. **7**, the device **20** is different from that of **10**. The difference includes the barrel portion and two additional screws. Referring to FIG. **8**, there is shown a short barrel portion **238** which is integrally attached to the front side **232** of the guide plate **214**, wherein the short barrel portion **238** is perpendicularly located at the center of the rectangular plate **214**. Two identical screw holes **233** and **235** are symmetrical relative to the center of the plate **214**, and are respectively located adjacent to the two opposite ends **228** and **230** on the longitudinal central line of the plate **214**. The same small holes and tips are also used with this embodiment, and since they assemble and function the same as previously described, and the description thereof will not be repeated.

Referring to FIG. **9**, there is shown a cross-sectional view of still another embodiment of the present invention improved odd angle internal fixation device. This embodiment is identical to the first embodiment as previously described in FIGS. **1** through **4** except that the short barrel portion **238** of the guide plate **214** is now at an angle "C" which is approximately 90 degrees, perpendicular to the guide plate **214**. In addition only the threaded wall **237** and opening wall **243** together defines a passage **252** of the barrel. The same elongated lag screw is used with this embodiment, and since it assembles and functions the same as previously described, the description thereof will not be repeated.

The present invention has many advantageous features, e.g., for the proximal humeral fracture, introduction of the internal fixation device into the bone is achieved through a small incision located below the attachment of the deltoid muscle where the humeral diaphysis is easily palpated. As a result, the need for deep dissection of the soft tissue in the proximity of the joint is eliminated. The improved odd angle internal fixation device can be manufactured in different sizes and used for similar fractures in a variety of joints. The improved odd angle internal fixation device may be used for solid fixation in osteotomies and in joint fusion. The

improved odd angle internal fixation device can also be manufactured with other preferred angles ranging approximately between 90 degrees to 170 degrees and be used for a variety of fractures, fusion procedures and osteotomies. The present invention conforms to prior disclosed forms of manufacture, however, has the improved structure including a curved plate to better fit bone cortex, a locking screw to secure the lag screw, one or two additional screws for additional force to compress the plate, and four tips on the front side of the plate for enhancing stability of the plate, to achieve user friendly and security objectives.

Defined in detail, the present invention is an improved internal fixation device for use in a transverse fracture of the humerus, or in a longitudinal surgical head fracture of the epiphysis to cross fix the fracture line, the internal fixation device comprising: (a) a generally rectangular shaped guide plate for abutting against a diaphysis cortex of the humerus on one side of the fracture and having a front side, a back side and a bore containing threads therethrough located adjacent to one end of the guide plate, the guide plate being slightly transversely curved wherein the front side is concave and the back side convex, the guide plate having four small holes extending perpendicularly through the guide plate and respectively located adjacent each corner of the rectangular plate, the front side of the plate further having four tips extending perpendicularly to the plate wherein each tip extends transversely from the back side to the front side of the plate and each tip is respectively located adjacent each corner of the rectangular plate, the tips located further away from each corner than the holes, the plate having a the first option to be used exclusively for fixing the transverse fracture and having one additional medium size hole for hosting a screw located at a position along a longitudinal center line of the plate close to a proximal end of a barrel portion, the plate having a second option to be used exclusively for fixing the longitudinal fracture and having two additional medium size holes to host two screws symmetrically located relative to the center of the rectangular plate, at the centerline of the plate close to two ends of the plate; (b) a short barrel portion with a cylindrical hollow structure having the length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and a distal end of the short barrel portion, the short barrel portion having a first option to be used exclusively for fixing the transverse fracture to have a distal end with an opening, a proximal end with an opposite opening, an inner sidewall adjacent to the opposite opening, an opening wall adjacent to the distal end, an inner cylindrical wall adjacent to the opening in the wall, and a threaded wall adjacent to the inner side wall, the inner sidewall and the threaded wall and the inner cylindrical wall and the opening wall in series defining a passage extending from a proximal end opening to the distal end opening, the internal diameter of the distal end opening wall being the smallest and also being slightly bigger than that of the threaded teeth of the distal thread of the lag screw, the diameter of the inner wall being the largest, and diameter of the threaded wall being intermediate, the length of the threaded wall being slightly less than a height of a locking screw, the length of the inner cylinder wall is the same as the length of the proximal head of the lag screw, the short barrel portion having a second option to be used exclusively for fixing the longitudinal fracture to have a distal end with an opening and proximal end with an opposite opening, a threaded wall adjacent to the opposite opening, an opening wall adjacent to the distal end, and an inner cylinder wall in between the threaded wall and the opening wall, the threaded wall and the inner cylindrical wall and the opening wall defining a passage extending from the proximal end opening to the distal end opening, the internal diameter of the distal end opening wall being the smallest, the diameter of the threaded wall the largest, the length of the threaded wall being slightly less than a height of the locking screw, and a length of the inner cylindrical wall is the same as a height of the proximal head of the lag screw; (c) said proximal end of the barrel portion integrally attached to the front side of the guide plate, such that the passage is communicating with the bore of the guide plate, the short barrel portion used for adapting within the diaphysis cortex of the humerus such that the front side of the guide plate is placed against the diaphysis cortex of the humerus, the barrel portion attached to the plate at a preferred inclined angle, the inclined angle having the first option exclusively for fixing the transverse fracture to be either 150 degrees or 160 degrees, said inclined angle having the second option exclusively for fixing the longitudinal fracture to be 90 degrees; (d) an elongated lag screw for internally cross fixing the fracture line and settling in the depth of the epiphysis and having a distal threaded portion and a proximal portion, the proximal portion having a proximal cylinder and a proximal head having a hexagonal cavity with means for receiving a driving tool in its top end, the diameter of the proximal cylinder being smallest, the diameter of the thread teeth of the distal threaded portion being larger than that of the proximal cylinder, and the diameter of the proximal head being the largest; (e) said lag screw being slidably received within the passage of the barrel portion and extending out of the barrel portion following a pre-drilled mall guide hole for cross fixing the fracture line of the diaphysis cortex of the humerus with the distal threaded portion of the lag screw being located within the depth of the epiphysis, the proximal head of the lag screw being press-fitted within the distal end opening of the barrel portion such that the proximal head of the lag screw is contacting the inner cylinder wall of the short barrel portion and rests within the barrel portion for preventing the proximal head from extending out of the barrel portion when the guide plate is compressed against the diaphysis cortex of the humerus, and the guide plate adapted for being fixed to the diaphysis cortex of the humerus by the lag screw and dissipates all of the compression forces of the internal fixation device; (f) said guide plate is also compressed by one additional screw from the first option exclusively for fixing the transverse fracture, and two additional screws from the second option exclusively for fixing the longitudinal fracture; and (g) a locking screw being applied into the cylindrical hollow passage of the barrel through the proximal end opening, said locking screw being pressed and turned to contact the surface of the head of the lag screw for securely locking in the lag screw residing in the epiphysis; (h) whereby the guide plate dissipates all of the compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

Defined more broadly, the present invention is an improved internal fixation device for use in a transverse surgical fracture of the humerus, or in a longitudinal surgical head fracture of the epiphysis to cross fix the fracture line, the internal fixation device comprising: (a) a generally rectangular shaped guide plate for abutting against the diaphysis cortex of the humerus on one side of the fracture, said guide plate being slightly curved wherein the front side is concave and back side convex, the guide plate having four small holes extending perpendicularly through the plate, and four tips extending perpendicularly to the plate, the holes and the tips respectively located adjacent each corner of the rectangular plate,

the guide plate further comprising a short barrel portion with a cylindrical hollow structure having the length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and a distal end of the short barrel portion, the short barrel portion further comprising a proximal end integrally attached to the front side of the low profile guide plate, the short barrel portion used for adapting within the diaphysis cortex of the humerus such that the front side of the guide plate is placed against the diaphysis cortex of the humerus, the barrel portion attached to the guide plate at a preferred inclined angle; (b) an elongated lag screw for internally cross fixing the fracture line and settling in the depth of the epiphysis and having a distal threaded portion and a proximal portion, the proximal portion having a proximal cylinder and a proximal head having a cavity with means for receiving a driving tool in its top end; (c) said lag screw being slidably received within the passage of the barrel portion and extending out of the barrel portion following a pre-drilled small guide hole for cross fixing the fracture line of the diaphysis cortex of the humerus with the distal threaded portion of the lag screw being located within the depth of the epiphysis, and the guide plate adapted for being fixed to the diaphysis cortex of the humerus by the lag screw; and (d) a locking screw being applied into the cylindrical hollow passage of the barrel through the proximal end opening, said locking screw being pressed and turned to contact the surface of the head of the lag screw for securely locking in the lag screw which resides in the epiphysis; (e) whereby the guide plate dissipates all of the compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

Defined even more broadly, the present invention is an improved internal fixation device for use in a transverse surgical fracture of the humerus, or in a longitudinal surgical head fracture of the epiphysis to cross fix the fracture line, the internal fixation device comprising: (a) a generally rectangular shaped guide plate for abutting against the diaphysis cortex of the humerus on one side of the fracture, the guide plate being curved, the guide plate having small holes extending perpendicularly through the plate and tips extending perpendicularly to the plate, said guide plate further comprising a short barrel portion with a cylindrical hollow structure having a length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and the distal end of the short barrel portion, said short barrel portion further comprising a proximal end integrally attached to the front side of the guide plate, said barrel portion attached to said guide plate at a preferred inclined angle; (b) a lag screw for internally cross fixing the fracture line having a distal threaded portion and a proximal portion, said lag screw being slidably received within the passage of the barrel portion and extending out of the barrel portion following a pre-drilled small guide hole for cross fixing the fracture line of the diaphysis cortex of the humerus, and when the guide plate is compressed against the humerus by the lag screw; and (c) a locking screw being applied to contact the surface of the head of the lag screw for securely locking the lag screw; (d) whereby the low profile guide plate dissipates all of the compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

Of course the present invention is not intended to be restricted to any particular form or arrangement, or any specific embodiment disclosed herein, or any specific use, since the same may be modified in various particulars or relations without departing from the spirit or scope of the claimed invention hereinabove shown and described of which the apparatus shown is intended only for illustration and for disclosure of an operative embodiment and not to show all of the various forms or modifications in which the present invention might be embodied or operated.

The present invention has been described in considerable detail in order to comply with the patent laws by providing full public disclosure of at least one of its forms. However, such detailed description is not intended in any way to limit the broad features or principles of the present invention, or the scope of patent monopoly to be granted.

What is claimed is:

1. An improved internal fixation device for use in a transverse fracture of the humerus, the internal fixation device comprising:

a. a generally rectangular shaped guide plate capable of abutting against a diaphysis cortex of the humerus on one side of the fracture and having a front side, a back side and a bore containing threads therethrough located adjacent to one end of the guide plate, the guide plate being slightly transversely curved wherein the front side is concave and the back side convex, the guide plate having four small holes extending perpendicularly through the guide plate and respectively located adjacent each corner of the rectangular plate, the front side of the plate further having four tips extending perpendicularly to the plate wherein each tip extends transversely from the back side to the front side of the plate and each tip is respectively located adjacent each corner of the rectangular plate, the tips located further away from each corner than the holes, the plate used exclusively for fixing the transverse fracture and having one additional medium size hole for hosting a screw located at a position along a longitudinal center line of the plate close to a proximal end of a barrel portion;

b. a short barrel portion with a cylindrical hollow structure having the length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and a distal end of the short barrel portion, the short barrel portion used exclusively to be capable of fixing the transverse fracture to have a distal end with an opening, a proximal end with an opposite opening, an inner sidewall adjacent to the opposite opening, an opening wall adjacent to the distal end, an inner cylindrical wall adjacent to the opening, and a threaded wall adjacent to the inner sidewall, the inner sidewall and the threaded wall and the inner cylindrical wall and the opening wall in series defining a passage extending from the proximal end to the distal end, an internal diameter of the opening wall being the smallest and also being slightly bigger than that of threaded teeth of a distal threaded portion of an elongated solid lag screw, a diameter of the inner sidewall being the largest, and a diameter of the threaded wall being intermediate, a length of the threaded wall being slightly less than a height of a locking screw, a length of the inner cylindrical wall is the same as a length of a proximal head of the lag screw;

c. said proximal end of the barrel portion integrally attached to the front side of the guide plate, such that the passage is communicating with the bore of the guide plate, the short barrel portion used for adapting within the diaphysis cortex of the humerus such that the front

side of the guide plate is placed against the diaphysis cortex of the humerus, the barrel portion attached to the plate at a preferred inclined angle, the inclined angle having the first option exclusively for fixing the transverse fracture to be either 150 degrees or 160 degrees;

d. said elongated solid lag screw capable of internally cross fixing the fracture line and settling in the depth of the epiphysis and having the distal threaded portion and a proximal portion, the proximal portion having a proximal cylinder and the proximal head having a hexagonal cavity with means for receiving a driving tool in said cavity, a diameter of the proximal cylinder being smallest, a diameter of threaded teeth of the distal threaded portion being larger than that of the proximal cylinder, and a diameter of the proximal head being the largest;

e. said lag screw being slidably received within the passage of the barrel portion and extending out of the barrel portion following a pre-drilled mall guide hole capable of cross fixing the fracture line of the diaphysis cortex of the humerus with the distal threaded portion of the lag screw being located within the depth of the epiphysis, the proximal head of the lag screw being press-fitted within the distal end opening of the barrel portion such that the proximal head of the lag screw is contacting the inner cylinder wall of the short barrel portion and rests within the barrel portion for preventing the proximal head from extending out of the barrel portion when the guide plate is compressed against the diaphysis cortex of the humerus, and the guide plate adapted to be capable of being fixed to the diaphysis cortex of the humerus by the lag screw and dissipates all of the compression forces of the internal fixation device; and

f. said locking screw being applied into the cylindrical hollow structure of the barrel through the proximal end opening, said locking screw being pressed and turned to contact the surface of the proximal head of the lag screw for securely locking in the lag screw residing in the epiphysis;

g. whereby the guide plate dissipates all of the compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

2. An improved internal fixation device for use in a transverse surgical fracture of the humerus, the internal fixation device comprising:

a. a generally rectangular shaped guide plate capable of abutting against the diaphysis cortex of the humerus on one side of the fracture, said guide plate being slightly curved wherein a front side is transversely concave and a back side is transversely convex, with the front side and back side being linear in the longitudinal direction, the guide plate having four small holes respectively located adjacent each corner of the plate and capable of positioning the device and four tips extending perpendicularly to the plate, the medium sized hole located adjacent one end of the guide plate and the tips respectively located adjacent each corner of the rectangular plate, the guide plate further comprising a short barrel portion with a cylindrical hollow structure having a length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and a distal end of the short barrel portion, the short barrel portion further comprising a proximal end integrally attached to the front side of the profile guide plate, the short barrel portion capable of adapting within the diaphysis cortex of the humerus such that the front side of the guide plate is placed against the diaphysis cortex of the humerus, the barrel portion attached to the guide plate at a preferred inclined angle;

b. an elongated solid lag screw capable of internally cross fixing the fracture line and settling in a depth of the epiphysis and having a distal threaded portion and a proximal portion, the proximal portion having a proximal cylinder and a proximal head having a cavity with means for receiving a driving tool in the cavity;

c. said lag screw being slidably and rotatably received within a cylindrical hollow passage of the barrel portion and extending out of the barrel portion following a pre-drilled small guide hole to provide a rotating and sliding forward movement relative to the guide plate to be capable of cross fixing the fracture line of the diaphysis cortex of the humerus with the distal threaded portion of the lag screw being located within a depth of the epiphysis, and the guide plate adapted to be capable of being fixed to the diaphysis cortex of the humerus by the lag screw, wherein the four tips are capable of penetrating through the cortex of the humerus to provide additional affixing forces to stabilize the device; and

d. a locking screw being applied into the cylindrical hollow passage of the barrel through a proximal end opening, said locking screw being pressed and turned to contact an entire portion of the top surface of the proximal head of the lag screw capable of securely locking in the lag screw which resides in the epiphysis;

e. whereby the guide plate dissipates all compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

3. The improved fixation device in accordance with claim **2** wherein said short barrel portion capable of fixing the transverse fracture and has a distal end with an opening, a proximal end with an opposite opening, an inner sidewall adjacent to the opposite opening, an opening wall adjacent to the distal end, and a threaded wall adjacent to the inner sidewall, and an inner cylindrical wall adjacent to the opening wall.

4. The improved fixation device in accordance with claim **2** wherein said inclined angle capable of fixing the transverse fracture to be either 150 degrees or 160 degrees.

5. The improved fixation device in accordance with claim **2** wherein said means for accommodating a driving tool is a cross cavity within the top of said proximal head.

6. The improved fixation device in accordance with claim **2**, wherein a top of the lag screw further comprises means capable of accommodating a driving tool which is a hexagonal cavity within a top of the proximal portion.

7. An improved internal fixation device for use in a transverse surgical fracture of the humerus, comprising:

a. a generally rectangular shaped guide plate curved in a transverse direction and linear in a longitudinal direction and capable of abutting against a diaphysis cortex of the humerus on one side of the fracture, the guide plate having a medium sized hole extending perpendicularly through the plate and tips extending perpendicularly to the plate, said guide plate further comprising a short barrel portion with a cylindrical hollow structure having a length of the barrel portion being sufficiently short so as not to cross the fracture line and also to rest a sufficient distance from the fracture line to leave a bone mass between the fracture line and the distal end of the short barrel portion, said short barrel portion further compris-

ing a proximal end which is integrally affixed to the front side of the guide plate and positioned at a fixed distance from said medium sized hole, said barrel portion integrally affixed to said guide plate at a preferred inclined angle;

b. a solid lag screw for internally cross fixing the fracture line having a distal threaded portion and a proximal portion with a head, said lag screw being slidably and rotatably received within a passage of the barrel portion and extending out of the barrel portion following a pre-drilled small guide hole to provide a rotating and sliding forward movement relative to said guide plate to cross fix the fracture line of the diaphysis cortex of the humerus, so that the guide plate is compressed against the diaphysis cortex of the humerus by the lag screw, wherein the tips are capable of penetrating through the cortex of the humerus to provide additional affixation forces to stabilize the device; and

c. a locking screw being applied to contact an entire top surface of the head of the lag screw for securely locking the lag screw;

d. whereby the low profile guide plate dissipates all of the compression forces of the internal fixation device that are applied against the diaphysis cortex of the humerus, and thereby the diaphysis cortex of the humerus remains healthy and intact.

8. The improved fixation device in accordance with claim **7** wherein said plate for fixing the transverse fracture has one medium sized hole, and a screw is threaded to be capable of penetrating through the medium sized hole of the guide plate and further to be capable of penetrating through the disphysis cortex of the humerus for providing additional fixation of the guide plate.

9. The improved fixation device in accordance with claim **7** wherein said short barrel portion capable of fixing the transverse fracture has an inner sidewall adjacent to an opposite opening, an opening wall adjacent to a distal end, and an inner cylinder wall and a threaded wall in between.

10. The improved fixation device in accordance with claim **7** wherein said inclined angle capable of fixing the transverse fracture is either 150 degrees or 160 degrees.

11. The improved fixation device in accordance with claim **7** wherein the top of the lag screw further comprises means for accommodating a driving tool which is a cross cavity within the top of said proximal head.

12. The improved fixation device in accordance with claim **7** wherein the top of the lag screw further comprises means for accommodating a driving tool which is a hexagonal cavity within the top of said proximal head.

13. The improved fixation device in accordance with claim **7**, further comprising: a screw is threaded to be capable of penetrating through the medium sized hole of the guide plate and further capable of penetrating through the disphysis cortex of the humerus for providing additional fixation of the guide plate.

14. The improved fixation device in accordance with claim **7**, further comprising four small sized holes respectively located adjacent each corner of the plate capable of providing assistance for positioning the device.

15. An improved internal fixation device for using to fix a transverse surgical fracture of the humerus, comprising:

a. a guide plate curved in a transverse direction and linear in a longitudinal direction and capable of abutting against a diaphysis cortex of the humerus on one side of the fracture, the guide plate having tips extending perpendicularly to the plate and a medium sized hole capable of fixing said guide plate to said diaphysis cortex, said guide plate further comprising a short hollow barrel portion having a length being sufficiently short so that said short hollow barrel portion does not cross the fracture, said hollow short barrel portion is integrally affixed to a front side of said guide plate with a preferred inclined angle and positioned at a fixed distance from said medium sized hole;

b. a solid lag screw capable of internally cross fixing the fracture line having a distal threaded portion and a proximal portion, said lag screw being rotatably and slidably received by said short hollow barrel portion and extending out of the barrel portion from a rotating and sliding forward movement relative to said guide plate to be capable of cross fixing the fracture line of the diaphysis cortex of the humerus, which causes said guide plate that is compressed to be affixed to the diaphysis cortex of the humerus, wherein the tips are capable of penetrating through the cortex of the humerus to provide additional affixation forces to stabilize the device; and

c. whereby said guide plate dissipates all of compression forces of said internal fixation device that are applied against said diaphysis cortex of the humerus, and thereby said diaphysis cortex of the humerus remains healthy and intact.

16. The improved fixation device in accordance with claim **15**, wherein the short barrel portion capable of fixing the transverse fracture has a passage having an inner sidewall adjacent to an opposite opening, an opening wall adjacent to a distal end, and an inner cylindrical wall and a threaded wall in between.

17. The improved fixation device in accordance with claim **15**, wherein said inclined angle capable of fixing the transverse fracture is either 150 degrees or 160 degrees.

18. The improved fixation device in accordance with claim **15**, wherein a top of the lag screw further comprises means for accommodating a driving tool which is a cross cavity within a top of the proximal portion.

19. The improved fixation device in accordance with claim **15**, wherein a top of the lag screw further comprises means for accommodating a driving tool which is a hexagonal cavity within a top of the proximal portion.

20. The improved fixation device in accordance with claim **15**, further comprising: a screw is threaded to be capable of penetrating through the medium sized hole of the guide plate and further be capable of penetrating through the disphysis cortex of the humerus for providing additional fixation of the guide plate.

21. The improved fixation device in accordance with claim **15**, further comprising four small sized holes respectively located adjacent each corner of the plate capable of providing assistance for positioning the device.

* * * * *

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(54) **PLATE FOR FUSION OF THE METATARSO-PHALANGEAL JOINT**

(76) Inventors: **Mark Myerson**, Baltimore, MD (US); **Priya Prasad**, Warsaw, IN (US); **Chris Bremer**, Warsaw, IN (US)

Correspondence Address:
Maginot, Moore & Beck LLP
Chase Tower, Suite 3250
111 Monument Circle
Indianapolis, IN 46204-5109 (US)

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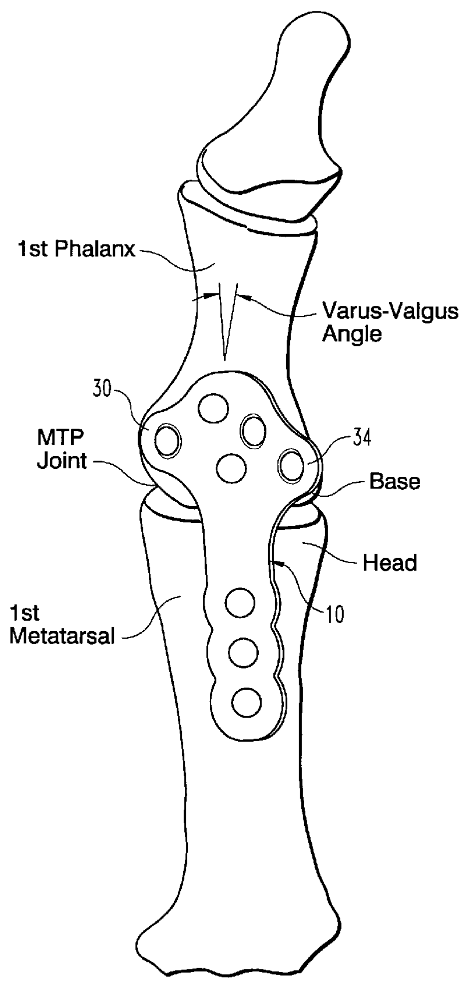
(57) **ABSTRACT**

A fixation plate for use in fusion of the metatarsal-phalangeal joint includes a distal portion configured to engage the metatarsus bone and a proximal portion configured to engage the phalanx bone. The distal portion is elongated with several screw defined therethrough along a longitudinal axis passing through the portion. The proximal portion includes a plurality of screw holes that are all offset relative to each other along axes parallel and perpendicular to the longitudinal axis. No more than one of the screw holes in the proximal portion is aligned with the longitudinal axis. The fixation plate is contoured to cup the bones of the MTP joint. The plate may include an intermediate portion that is bent at a pre-determined dorsi-flexion angle.



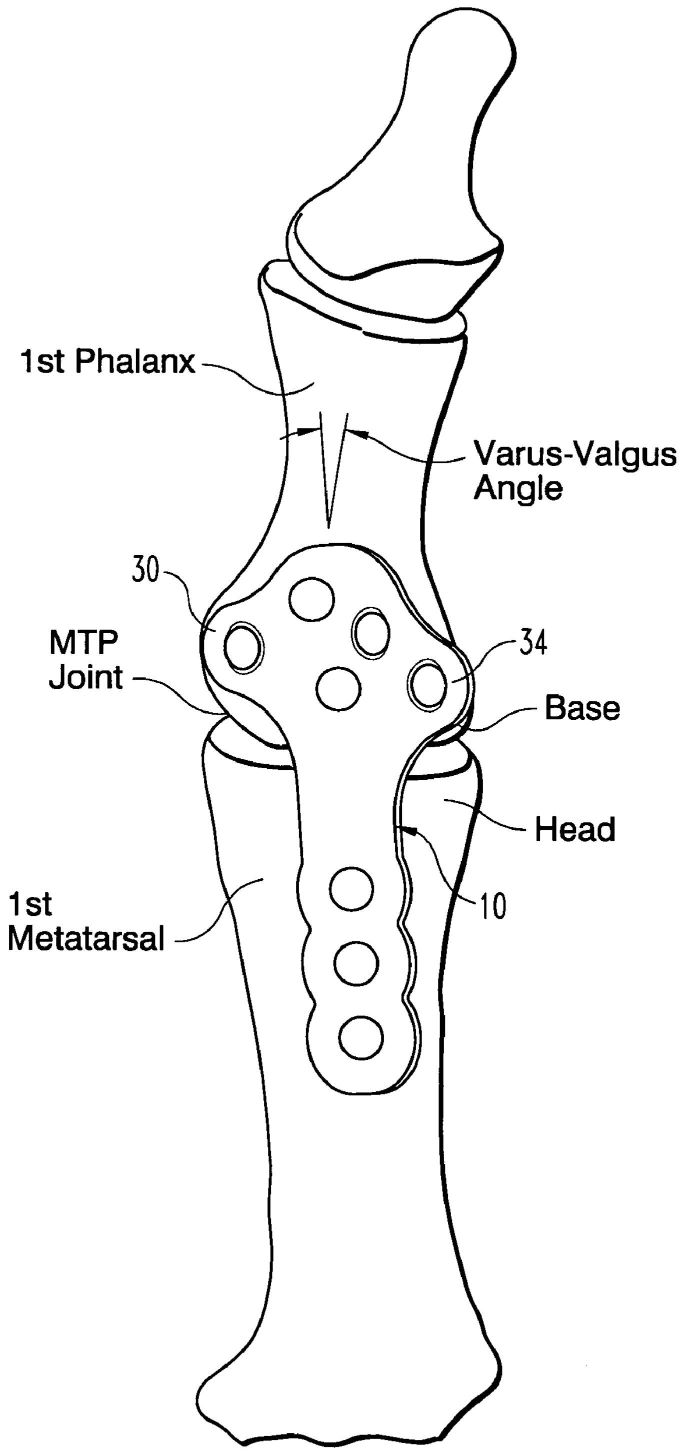

1st Phalanx
Varus-Valgus Angle
30
MTP Joint
34
Base
Head
10
1st Metatarsal

Fig. 1

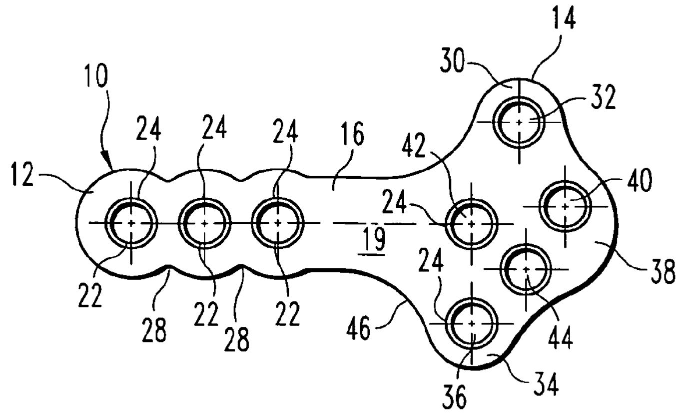


Fig. 2

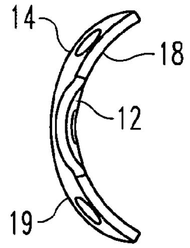


Fig. 5

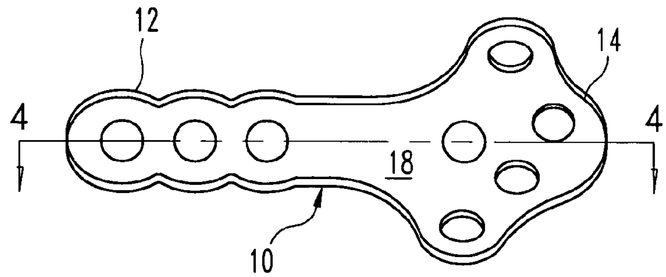


Fig. 3

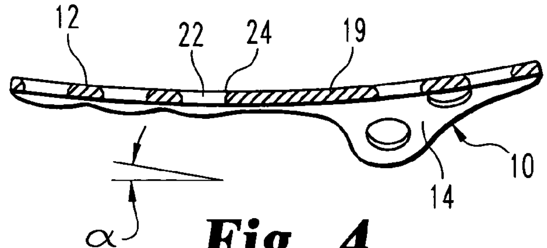


Fig. 4

PLATE FOR FUSION OF THE METATARSO-PHALANGEAL JOINT

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the general technical field of surgical devices for fixing together and aligning the two bony parts of a joint relative to each other, and in particular a metatarso-phalangeal joint, in order to perform arthrodesis.

[0002] Arthrodesis or fusion of the first metatarso-phalangeal (MTP) joint is often the treatment of choice for several indications, such as hallux valgus, hallux limitus or rigidus, degenerative joint disease, severe dislocation or subluxation, and degenerative deformities. Fusion can be used to correct deformities associated with these indications or to alleviate joint pain associated with movement of the MTP joint. Fusion of the first MTP joint allows the patient to walk without discomfort, usually with minimal impact on gait pattern. In fact, where the indicated pathology led to a significant disruption in the patient's ability to walk, fusion may actually improve the patient's gait pattern.

[0003] As a general rule, arthrodesis can be problematic because it results in a joint position that is defined and irreversible. Thus, it is very important for arthrodesis of an MTP joint to be performed carefully so that the two bones will be accurately positioned relative to each other to avoid any subsequent difficulty and to preserve the patient's ability to walk as normally as possible.

[0004] In one common fusion procedure, the articulating aspects of the metatarsal bone and phalanx are prepared as necessary so that the bones can be positioned at appropriate dorsi-flexion and varus-valgus angles. Then a pair of bone fasteners, such as 4-0 cannulated screws, are implanted across the MTP joint to fix the joint position. Bone graft may be introduced in areas of bone separation to facilitate complete fusion of the joint.

[0005] In one alternative, a fixation plate is implanted across the joint and is typically fastened to the opposing bones by bone screws. The fixation plate is bent by the surgeon to achieve an angle in the dorsi-flexion plane that is specific to the patient, thereby reducing difficulty for the patient while walking and minimizing possible future complications. Many prior plates are unsuitable for bending through a varus-valgus angle, which means that they are not capable of implementing arthrodesis that is sufficiently close to the optimum anatomic orientation of the two bones to be fused together.

[0006] More recently, fixation plates have been provided that are pre-formed with a fixed varus-valgus angle and a fixed dorsi-flexion angle. An example of this type of plate is the HALLU®-C Plate offered by Newdeal SA. This plate constitutes two linear plate sections aligned at a fixed ten degree varus-valgus angle relative to each other. The plate is also bent at its mid-line to form a ten degree dorsi-flexion angle. Each linear plate section includes an elongated slot flanked by two screw holes arranged along the longitudinal axis of the section. Other details of this plate appear in published application US2003/0060827, published on Mar. 27, 2003, the disclosure of which is incorporated herein by reference.

[0007] Fixation plates of this type represent an improvement over prior plates that required the surgeon to bend the plate at the dorsi-flexion angle during the surgical procedure and that do not permit any varus-valgus angle. However, there is still room for improvement in fixation plates for the MTP joint, especially for the first MTP joint. In particular, there is a need for a fixation plate that provides greater flexibility in positioning the bone fasteners fixing the plate to the associated bones, especially the phalanx. There is also a need for a fixation plate that presents a lower profile to minimize soft tissue irritation.

SUMMARY OF THE INVENTION

[0008] The present invention satisfies the need for an improved fixation plate for arthrodesis of the metatarsal-phalangeal joint. In one embodiment of the invention, the plate includes a metatarsal portion that is generally elongated to extend along the distal length from the head of the metatarsus bone. A series of chamfered screw holes extend along the axis of the metatarsal portion.

[0009] The plate further includes a phalanx portion connected to the metatarsal portion by an intermediate portion of the plate. The phalanx portion is enlarged and asymmetric relative to the elongated metatarsal portion. In the preferred embodiment, the phalanx portion includes a medial wing and an opposite lateral wing that is axially offset from the medial wing. Each wing supports a chamfered screw hole. A central region between the two wings also supports thee screw holes, laterally and axially offset from each other.

[0010] In a further aspect of the invention, the entire plate is curved to provide a curved bone engaging surface that generally follows the contour of the metatarsal bone and phalanx. Rather than incorporate a pre-determined varus-valgus angle offset between the metatarsal portion and phalanx portion of the plate, the fixation plate of the present invention is configured so that the phalanx portion cups the proximal end or base of the phalanx and the metatarsal portion simply overlays the distal portion of the metatarsus bone to be fixed to the bone at whatever angle is dictated by the orientation of the phalanx portion fixed to the base of the phalanx. In the preferred embodiment, the plate is bent at the intermediate portion to an appropriate dorsi-flexion angle.

[0011] In order to minimize the profile of the plate, the present invention contemplates a plate thickness of about 1 mm. In addition, the perimeter of the plate is contoured about the screw holes to reduce the amount of material across the surface of the plate.

[0012] One benefit of the present invention is that it provides a plate for arthrodesis of the MTP joint that can be firmly fixed to the bones of the joint. Another benefit is that the plate provides for a variety of screw fixation points, especially across the base of the phalanx.

[0013] A further benefit achieved by the fixation plate of the present invention is that is exhibits a minimal profile to reduce its prominence over the bones and minimizes tissue irritation. These and other benefits of the invention will be appreciated upon consideration of the following written description together with the accompanying figures.

DESCRIPTION OF THE FIGURES

[0014] **FIG. 1** is a top view of the metatarsal-phalangeal joint with a fixation plate situated thereon in accordance with one embodiment of the present invention.

[0015] **FIG. 2** is a top flat pattern view of the fixation plate shown in **FIG. 1**.

[0016] **FIG. 3** is a bottom view of the fixation plate illustrated in **FIG. 1**, especially showing the curvature of the bone engaging surface of the plate.

[0017] **FIG. 4** is a longitudinal cross sectional view of the plate shown in **FIG. 3**, taken along line **4-4** as viewed in the direction of the arrows.

[0018] **FIG. 5** is an end view of the plate depicted in **FIG. 3**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0019] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

[0020] The distal bones of the first toe, or great toe, are shown in **FIG. 1**. In particular, the toe includes a first metatarsal bone, a first phalanx bone and a metatarsal-phalangeal (MTP) joint therebetween. A fixation plate **10** according to one embodiment of the present invention spans the MTP joint and is configured to be fixed to both bones of the joint. As shown in more detail in **FIG. 2**, the plate **10** includes a distal or metatarsal portion **12** and a proximal or phalanx portion **14**. An integral intermediate portion **16** connects the distal and proximal portions.

[0021] The distal portion **12** is generally elongated with at least two, and most preferably three, holes **22** positioned substantially along the longitudinal axis of the portion. The holes **22** are configured to receive the shank of a bone fastener, such as a bone screw. In one aspect of this embodiment, the holes **22** include a circumferential chamfer **24**. This chamfer allows the use of two different sizes of bone screw. In a specific embodiment, the holes **22** have a diameter of 3.8 mm with a 120 degree chamfer **24** to produce a proximal diameter of 5.3 mm. This specific screw hole is configured to receive either 2.7 mm or 3.5 mm cortical screws.

[0022] In the illustrated embodiment, the screw holes **22** are configured to receive non-locking screws. In an alternative embodiment, the screw holes are designed to receive locking screws, such as by the incorporation of locking threads (not shown) within the screw hole. The locking threads can be of a variety of known configurations as dictated by the particular cortical locking screw. In a specific embodiment, the locking threads may be at 0.5 mm pitch, with a 4.0 mm major diameter and a 3.6 mm minor diameter.

[0023] In the preferred embodiment of the invention, the screw holes **22** are spaced at 6.0 mm intervals. In one aspect of the invention, the perimeter **28** of the distal portion **12** is contoured around the screw holes to reduce the plate material in the area around the holes that does not carry any appreciable load.

[0024] The proximal or phalanx portion **14** of the plate is asymmetric, as best seen in **FIG. 2**. In the preferred embodiment, the proximal portion includes a medial wing **30** and an opposite lateral wing **34**. The two wings are axially offset from each other, with the medial wing being positioned more proximal than the lateral wing. The configuration of the wings **30**, **34** generally correspond to the orientation of the base of the first phalanx when the phalanx is positioned at an acceptable varus-valgus angle, as shown in **FIG. 1**. An acceptable varus-valgus angle may range from 5-10 degrees, with five degrees being most preferred for the majority of patients. At this angle, the medial aspect of the base of the phalanx is more proximal than the lateral aspect. This offset is accounted for in the plate **10** by the axial offset between the medial and lateral wings.

[0025] Each wing supports a corresponding screw hole **32**, **36**. The screw holes are preferably configured like the screw holes **22** described above to include the circumferential chamfer **24**. The screw holes **32**, **36** may accept locking or non-locking cortical screws, as described above. As with the screw holes in the distal portion **12**, the perimeter of each wings **30**, **34** is contoured around the corresponding screw holes **32**, **36**, to reduce the plate profile or prominence above the bone and minimize soft tissue irritation.

[0026] The proximal portion **14** includes a central region **38** between the two wings. In the preferred embodiment, the central region **38** includes three screw holes **40**, **42** and **44**. The center of each of these screw holes is axially and transversely offset relative to each other, as well as relative to the screw holes **32**, **36** in the wings. The screw hole **42** may be axially aligned with the screw holes **22** in the distal portion **12** of the plate **10** and/or along the longitudinal axis of the distal portion.

[0027] In the preferred embodiment, the proximal portion **14** of the plate includes five screw holes **32**, **36**, **40**, **42** and **44**. The screw holes are arranged so that a screw can be threaded into the phalanx through each hole without conflict. The surgeon may select all or any subset of the screw holes for fixation of the plate **10** to the phalanx. This flexibility in screw placement is particularly beneficial for patients with osteopenic bone, where a portion of the bone has been resected or in cases where the base of the phalanx has been fractured. Moreover, the arrangement of the screw holes across the proximal portion **14** allows the surgeon to select a minimum of two screw positions that optimally affixes the plate **10** to the bone. In other words, with the five screw holes in the proximal portion, the surgeon can introduce two bone screws in ten different orientations (e.g., placing a screw in holes **32** and **36**, or in holes **40** and **36**, or in holes **42** and **44**).

[0028] It can be appreciated that the arrangement of screw holes in the plate **10** accommodates any varus-valgus angle at the time of implantation. In one method for implanting the plate **10**, the surgeon determines the number of screws necessary for strong attachment of the plate to the phalanx. The proximal portion **14** of the plate is positioned on the phalanx and the bone screws are driven into the bone to attach the plate to the bone. (It is understood that the bone is prepared to receive the bone screws according to accepted practice, such as by pre-drilling and tapping a bore in the bone). With the proximal portion attached to the phalanx, the phalanx can be positioned at an acceptable varus-valgus

angle. In so doing, the distal portion **12** of the plate **10** will shift position relative to the metatarsal bone, but will always maintain sufficient contact with the bone.

[**0029**] Once the acceptable phalanx-metatarsal bone angle has been achieved, the distal portion **12** may then be attached to the metatarsal bone using any combination of bone screws in the screw holes **22**. It can therefore be appreciated that the fixation plate **10** of the present invention eliminates the difficulty associated with prior fusion plates in achieving or accommodating an acceptable varus-valgus angle. The plate **10** accepts any angle desired by the surgeon and does not enforce a pre-determined varus-valgus angle like prior plates. With the screw hole arrangements of the plate **10** of the present invention, the surgeon can produce valgus angles ranging from about five degrees to about ten degrees for fixation of the first toe.

[**0030**] This aspect of the plate **10** also facilitates manufacture of the plate. In one manner of making the plate, a sheet of material may be stamped into the flat pattern shape shown in **FIG. 2**. The necessary edge and surface treatments (such as deburring and anodizing) are easily accomplished on the flat pattern. The flat pattern may then be bent over a mandrel to introduce the curvature of the bone engaging surface **18**, as well as the upper surface **19** curvature, as both described below.

[**0031**] In a further feature of the fixation plate **10**, the bone engaging surface **18** of the plate may be contoured at a radius approximating the surface of the bone, as shown in **FIGS. 3 and 5**. In a preferred embodiment, both the entire plate **10** is contoured along its length at a radius of about 9.3 mm. In other embodiments, only the proximal portion **14** is contoured to fit the base of the phalanx. In addition to reducing the prominence of the fixation plate **10** above the bone, the contoured surface **18** also acts to "cup" the bone, especially the base of the phalanx. This "cupping" feature enhances the fixation of the plate to the bone, helps reduce fractures in the phalanx and helps align the bone screw axis to produce maximum engagement within the bone.

[**0032**] In addition to the contour of the surface **18**, the plate may also incorporate a curvature of the upper surface **19** along the length of the plate, as best seen in **FIG. 4**. This gradual curvature helps maintain a solid contact between the plate **10** and the two bones of the joint. In a specific embodiment, the plate is curved at a radius of about 130 mm over the length of the plate.

[**0033**] The fixation plate **10** preferably incorporates a pre-determined dorsi-flexion angle α, as shown in **FIG. 4**. In particular, the plate is bent at the intermediate portion **16** so that the bend can be oriented at the MTP joint between the two bones. In a most preferred embodiment, the plate is pre-bent at a dorsi-flexion angle of about 17 degrees for the first toe, which has been found to be anatomically optimal for most patients. However, the plate **10** can be offered pre-bent at other dorsi-flexion angles, and may even be bent by the surgeon to a different angle.

[**0034**] The plate **10** is formed of any medical grade material that is sufficiently strong to support the toe until fusion is achieved. In the preferred embodiment, the plate is formed of a titanium alloy, such as TI-6AL-4V. In order to maintain a minimal profile, the plate has a thickness of about 1 mm.

[**0035**] In the illustrated embodiment, the plate **10** is configured for the right foot of the patient. It is of course understood that a plate for the left foot will assume a mirror image of the plate shown in **FIGS. 1-3**.

[**0036**] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A fixation plate for fusion of the metatarsal-phalangeal (MTP) joint between a metatarsal bone and a phalanx bone, said plate comprising:

an elongated distal portion configured for attachment to the metatarsal bone, said distal portion defining at least one distal opening along a longitudinal axis passing through said distal portion, said at least one distal opening configured to receive a bone engaging fastener therethrough; and

a proximal portion connected to said distal portion and defining a plurality of proximal openings configured to receive a bone engaging fastener therethrough, wherein no more than one of said plurality of openings is aligned with said longitudinal axis.

2. The fixation plate according to claim 1, wherein said proximal portion includes a pair of opposite wings laterally offset from said longitudinal axis, each of said wings including one of said plurality of proximal openings.

3. The fixation plate according to claim 2, wherein said proximal portion further includes a central region between said wings, said central region defining at least one of said plurality of proximal openings.

4. The fixation plate according to claim 3, wherein said central region defines three of said plurality of proximal openings.

5. The fixation plate according to claim 4, wherein all of said proximal openings are offset relative to each other along an axis parallel to said longitudinal axis.

6. The fixation plate according to claim 5, wherein all of said proximal openings are offset relative to each other along an axis perpendicular to said longitudinal axis

7. The fixation plate according to claim 1, wherein at least said proximal portion exhibits a curvature in a surface of said proximal portion contacting the phalanx bone adapted to generally conform to the surface of the bone.

8. The fixation plate according to claim 1, wherein said plate exhibits a curvature along said longitudinal axis away from the MTP joint.

9. The fixation plate according to claim 1, wherein at least some of said distal and proximal openings include a circumferential chamfer at the surface of said plate opposite the MTP joint.

10. The fixation plate according to claim 1, further comprising an intermediate portion connecting said proximal portion to said distal portion, wherein said intermediate portion does not include any openings for receiving a bone engaging fastener therethrough.

11. The fixation plate according to claim 10, wherein said plate is bent at said intermediate portion at a pre-determined dorsi-flexion angle.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRIAL AND APPEAL BOARD

OSTEOMED, LLC,	)	
	)	
Petitioner,	)	IPR2022-00487
	)	US Patent 9,078,713
vs	)	
	)	IPR2022-00488
STRYKER EUROPEAN	)	US Patent 10,993,751
OPERATIONS HOLDINGS LLC,	)	
	)	
Defendants.	)	

The deposition of
KARL R. LEINSING, MSME, PE
called for examination at 500 West Madison Street, 34th Floor, Chicago, Illinois, on January 18, 2023 at the hour of 9:00 a.m.

STENOGRAPHICALLY
REPORTED BY: JO ANN LOSOYA, CSR, RPR, CRR
LICENSE #: 084-002437

BY THE WITNESS:

A. I wouldn't say that the hole 25 is or the axis of hole 25 is along the length of the Arnould. Or how do we spell that.

Q. I think it is Arnould because it's French. That's how we've been pronouncing it.

A. A-R-N-O-U-L-D. English would be Arnold.

Q. So looking at hole 25, would you consider this to be between the grouping of holes at one end and the other. So the holes -- I believe they're numbered 4 at one end and 3 at the other, would you consider hole 25 to be between holes 4 and 3?

A. No.

Q. Is that because the arm is in a different plane than the body of the plate?

MR. SURRETTE: Objection, scope and form.

BY THE WITNESS:

A. It's in a different plane, and it's offset and its axis to the hole is not in any relation to the main part of the Arnould plate.

Q. So if you bent that leg up, that leg 20, to be in the same plane as the rest of the plate, would hole 25 be between holes 4 and 3?

MR. SURRETTE: Objection, scope and form.

BY THE WITNESS:
A. No.
Q. Why not?
A. Because it wouldn't be between those holes. It wouldn't lie in the space between the holes or the screws shown as 4 and 3, and I define between in the claim construction section of my declaration.
Q. What definition have you provided for between?
A. In Paragraph 36, I talk about "the claim term 'between' should be construed in a manner consistent with its ordinary meaning to a person of skill in the art at the time of the invention. Here, the ordinary meaning of 'between' is 'at, into, or across the space separating two objects, places, or points.'"
Q. So in your opinion in order for hole 25 to be between hole 3 and hole 4, 25 would need to be located on the body of the plate?
MR. SURRETTE: Objection, form.
BY THE WITNESS:
A. It would need to be on that main body of the Arnould plate and then have the other requirements as required by the claims.

UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRIAL AND APPEAL BOARD

OSTEOMED, LLC,)
)
Petitioner,)
)
vs.) IPR2022-00488
)
STRYKER EUROPEAN OPERATIONS,)
HOLDINGS, LLC,)
)
Patent Owner.)

Deposition of GEORGE B. HOLMES, JR., M.D., FAAOS, taken before NADINE J. WATTS, CSR, RPR, and Notary Public, pursuant to the Federal Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, at Suite 3500, 500 West Madison Street, in the City of Chicago, Cook County, Illinois, at 9:05 a.m. on the 20th day of January, A.D., 2023.

answer I just gave you with regard to the question you just asked.

MS. BEANE: Q If you could pull out the Arnould reference.

A What exhibit is that please?

Q I believe it's 1006.

If you turn to figure 1 in Arnould, which is also on page 23 of your declaration. In your declaration, on page 23, you've highlighted in green the slot 16. Do you see that?

A Yes.

Q And you've highlighted in yellow the screw 2 that's going through that slot 16. Do you see that?

A Yes.

Q Do you see the hole just to the right of what you've identified in green that's unlabeled?

A I see a circle to the right-hand side of the green that is unlabeled.

Q Do you know what that is?

A It has not been identified for that -- for the purpose of answering your question.

Q As a person of skill in the art, do you know what that is?

MR. SURRETTE: Objection, form, scope.

THE WITNESS: No.

MS. BEANE: Q If you saw a bone plate like this in the operating room, would you know what that is?

MR. SURRETTE: Objection, form and scope.

THE WITNESS: I don't think I have the ability to opine an answer to that question.

MS. BEANE: Q If you look at figure 2 in Arnould, which is on the following page, do you see that similar unlabeled hole to the right of the hole 16?

A Yes.

Q Is your answer the same with respect to that hole, that you don't know what it is?

A That's correct.

Q Is it possible those are holes used for temporary fixation devices?

MR. SURRETTE: Objection to form and to scope.

THE WITNESS: I have opined in your first question I don't know what that is. It's unlabeled. So I'm unable to answer that question.

MS. BEANE: Q If you could turn to Myerson Exhibit 1008. Do you see on the first page there's a figure, which is also figure 1 on the second page? It's a little bigger if you want to look at that instead. Do you see on the phalanx end of the plate of Myerson

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC.
Petitioners,

v.

OSTEOMED LLC,
Patent Owner

Case IPR2021-01450

U.S. Patent No. 8,529,608

PETITION FOR *INTER PARTES* REVIEW

Arnauld is directed to an arthrodesis plate for use in the lower extremities and specifically recognizes that bone plates used for the lower extremities are particularly prone to screw back-out due to loading conditions and constant use of the foot. (EX1008, ¶3) (repetition of bending stress "weakens the bone anchorage of the screws holding the plate against the fused bones"). Thus, for the same reasons set forth in Ground 2 with respect to Slater and Weaver, at the time of the invention, a POSITA would have been motivated to include Weaver's threaded screw holes in the Arnauld plate as modified by Slater to include a thickened bridge portion and a thickened portion surrounding the transfixation screw hole. (EX1002, ¶¶312-318). Moreover, a POSITA would have had a reasonable expectation of success in combining Arnauld, Slater and Weaver given that locking screws with threaded heads that mated with threads in the plate holes were common at the time. (EX1002, ¶318; EX1005, 8:35-9:1). It would have been obvious to a POSITA to configure the inner surface of the Arnauld transfixation screw hole (claim 6) and the inner surface of at least one of the Arnauld attachment points (claim 8), as modified by Slater, to lockably engage the head of a locking screw as described in Weaver to ensure stability and to prevent screw back-out. (Ex. 1002, ¶317).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC
Patent Owner.

Case No. IPR2022-00487

Patent No. 9,078,713

DECLARATION OF KARL R. LEINSING, MSME, PE IN SUPPORT OF PATENT OWNER'S RESPONSE

Mr. Sherman does not provide an opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 1 and 8 in arriving at claim 38. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

163. Thus, Slater and Zahiri do not render obvious claim 38.

XIII. GROUND 4: ARNOULD AND ZAHIRI DO NOT RENDER OBVIOUS CLAIMS 32, 33, AND 36-39

164. In my opinion, Arnould and Zahiri do not render obvious claims 32, 33, and 36-39 of the 713 patent.

A. A POSITA Would Not Have Been Motivated To Combine Arnould and Zahiri

165. Mr. Sherman offers the opinion that claims 32, 33, and 36-39 are obvious in view of the combination of Arnould and Zahiri. (EX1002, ¶189). I disagree. Mr. Sherman's "Basis for the Combination of Arnould and Zahiri" and analysis of the challenged claims does not establish that a POSITA would have been motivated to combine Arnould and Zahiri.

1. Arnould And Zahiri Are Not Analogous Art

166. Mr. Sherman concluded that "Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone. . . . Arnould and Zahiri are therefore in analogous fields of invention." (EX1002, ¶191). I disagree. While Arnould discloses a bone plate,

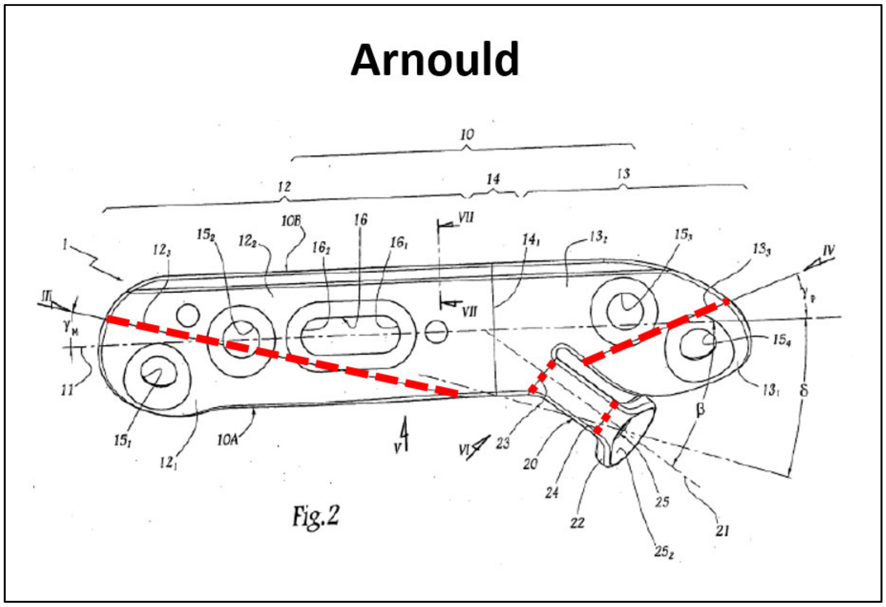
Zahiri does not. (Section V.C.). For the reasons explained above in Ground 3, Zahiri is not directed to a "bone plate" as claimed and is therefore, non-analogous art. (Section XII.A).

2. Zahiri Teaches Away From Arnould

167. Mr. Sherman also opines that "Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri." (EX1002, ¶193). In my opinion, Arnould's disclosure does not guide a POSITA anywhere near Zahiri. In fact, combining Zahiri with Arnould would remove a surgeon's ability to adjust the Arnould plate to a patient's anatomy.

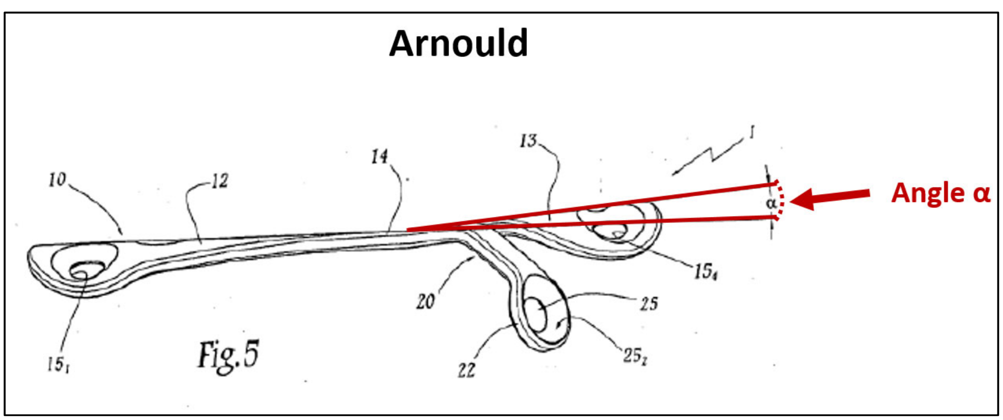
168. The Arnould plate is specifically designed for fusing the metatarsophalangeal (MTP) joint, "particularly for the joint between the first metatarsal and the first phalanx of the big toe." (EX1006, ¶1). Due to the shape and contours of the first metatarsal and the proximal phalanx, as well as the angle between the two bones, the Arnould plate is designed to be cut and bent by a surgeon to account for such anatomical variation. (EX1006, ¶¶15, 16, 17, 20, 23, 24, 25, 38, 39). For example, Arnould discloses that "[t]his plate is, in a first step, cut in accordance with predetermined contours in order to secure the metatarsal 12 and phalangeal 13 parts, as well as the leg 20. The various holes 151 to 154 and the oblong hole 16 are drilled in a second step. In a third step, sections 121 and 131 are bent while the plate is folded along lines 123, 133, 23 and 24." (EX1006, ¶38). I

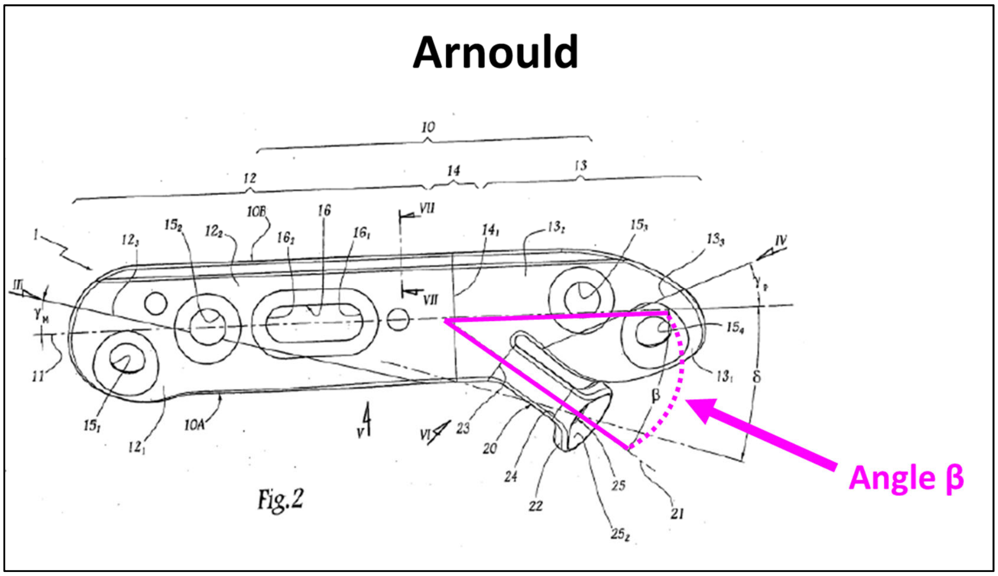
have indicated the referenced fold lines of Arnould below:



(EX1006, Fig. 2).

169. Arnould also discloses that the plate is bent within a range of two specific angles, α and β, to address (1) "the anatomical angle of dorsi-flexion between the metatarsal M and the phalanx P," and (2) "enveloping the phalangeal epiphysis P1 as closely as possible," respectively. (EX1006, ¶¶25, 38).





(EX1006, Fig. 5, Fig. 2).

170. These features provide a surgeon with a wide range of options with respect to cutting, contouring, bending, and adjusting the angle of the plate to fit the shape and alignment of the first metatarsal and proximal phalanx. However, when asked whether a surgeon could use plate benders to modify Zahiri, Mr. Sherman confirmed that Zahiri does not share the same pliable aspects as the Arnould plate. (EX2009, 158:7-13 ("Q. Could a surgeon use plate benders to modify Zahiri? . . . A. I don't know that Zahiri addresses it, but probably not. It just generally appears to be too short of a space and intended to be on a flat surface as well.")). I agree with Mr. Sherman. A POSITA would understand that Zahiri could not be adjusted to a patient's anatomy in the same way as Arnould and would therefore not be motivated to combine Zahiri with Arnould.

171. In making the alleged combination, Mr. Sherman states only that Zahiri "discloses an improved system that allows a sufficient amount of force to be applied between two bone parts" but nowhere does he opine on how combining Zahiri with Arnould would effect a surgeon's ability to contour and adapt the Arnould plate according to a metatarsophalangeal joint. (EX1002, ¶193). Of course, according to Mr. Sherman, Zahiri is not actually an "improved system" so it remains unclear why a POSITA would have been motivated to combine Zahiri with Arnould in the first place. (EX2009, 134:17-19 ("[i]f I said Zahiri is an improved system, I misspoke because Zahiri is . . . not focused at arthrodesis.")). Thus, a POSITA would not have been motivated to combine Arnould with Zahiri.

172. Mr. Sherman concedes that "Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate" and therefore combines Zahiri's "third hole at an angle relative to the longitudinal axis of the bone plate." (EX1002, ¶193). Mr. Sherman also states that "Zahiri discloses a bone plate configured to fuse a first and second bone part with an angled fixation member and compress the bone fracture." (*Id.*). However, a POSITA would understand that incorporating Zahiri's barrel portion into Arnould takes away the ability to select multiple trajectories for the cross screw of Arnould.

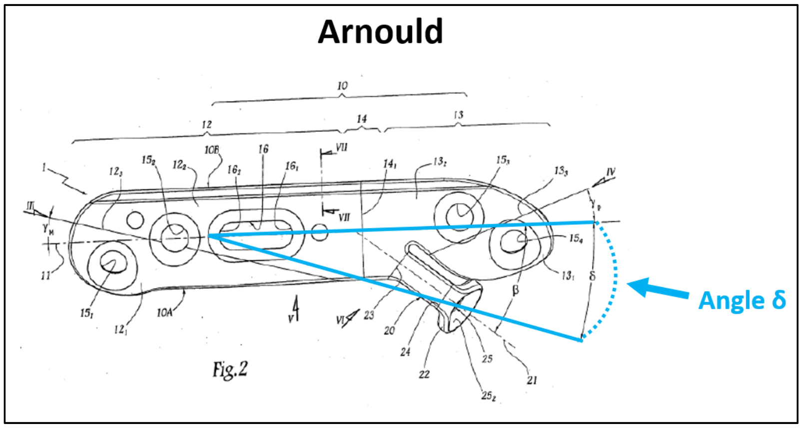
173. As discussed above in Section XII.A, Zahiri teaches that the barrel portion and guide plate are set at a fixed angle, which permits only one angle for the

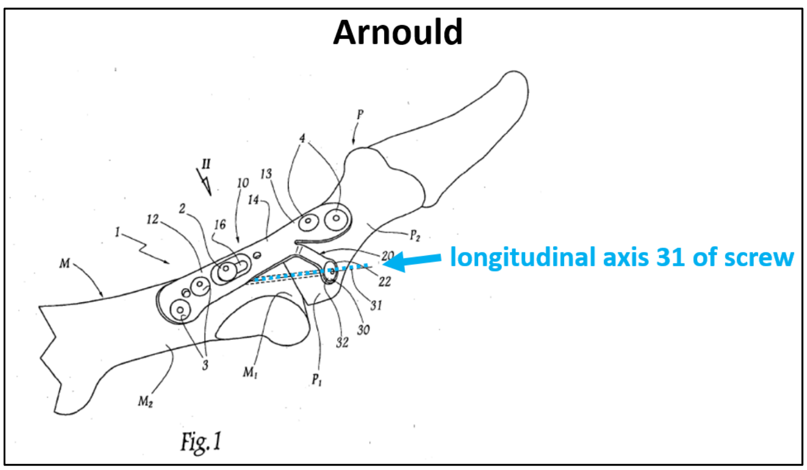
screw. (EX1007, Fig. 4, Fig. 5, Fig. 9, :23-28, 2:31-33, 3:26-31, 3:53-58, 6:12-25, 7:24-29, 7:31-35). For example, Zahiri discloses that "[t]he lag screw 12 is then slidably received within the passage 52 of the barrel portion 38 from the back 25 side 34 of the guide plate 14, where the interior of the short barrel portion 38 is designed so that the lag screw 12 engages into the barrel portion 38 at three different diameters of the passage 52." (EX1007, 7:24-29). The engagement between the geometry of Zahiri's lag screw and the barrel portion limits a surgeon's ability to insert the lag screw within a range of angles. (*Id.*; *see also id.,* 6:12-35).

174. This is different than hole 25 of Arnould, which permits a range of multiple trajectories for the screw. (EX1006, ¶¶27, 28). Even Mr. Sherman admitted that Arnould's screw can be inserted at a range of trajectories. (EX2009, 67:24-68:8 ("I think the screw can go in and move through a range [of] trajectories." Q. Setting aside whether we're talking about delta or beta, you would agree with me that the screw can go in at different trajectories of the screw, for instance? A. I think that's correct.")). While Arnould discloses that a single bone plate is capable of achieving a range of multiple trajectories for the screw, Zahiri discloses three embodiments, each including a barrel portion fixated at three separate angles: 90 degrees, 150 degrees, or 160 degrees. (EX1007, 2:23-28, Fig 4, 4:24-25, Fig. 5, 4:28, Fig. 9, 4:43; *see* Section XII.A *supra.*).

175. In particular, Arnould discloses that the screw is "inserted into the hole

25, following a direction of insertion inclined in relation to the plate body 10 at angle δ." (EX1006, ¶32). As shown below, δ is formed by the longitudinal axis 31 of the screw and the longitudinal direction 11 of the plate body 10. (*Id.*, ¶27).





(EX1006, Fig. 1, Fig. 2).

176. Arnould also discloses that angle δ "is chosen by the surgeon so that that this screw, during its screwing, successively passes through the phalangeal epiphysis P1 and the metatarsal epiphysis M1." (*Id.*, ¶32). Mr. Sherman acknowledges this and states that "Arnould further discloses a variable fixation angle

. . . selected by the surgeon." (EX1002, ¶192). Zahiri, however, does not provide the surgeon with the same flexibility. (EX2009, 90:24-91:9). If combined with Arnould, a POSITA would understand that a surgeon would not be able to choose from among the multiple screw trajectories afforded by hole 25, defeating one of the main advantages of the Arnould plate.

3. No Reasonable Expectation Of Success

177. Moreover, Zahiri teaches structural features that confine the head of Zahiri's lag screw. Features such as inner cylindrical wall 41, opening side wall 43, threaded side wall 37, and locking screw 13, which "is introduced on top of the lag screw head to securely lock the lag screw," are incompatible with the Arnould plate. (EX1007, 6:21-24; EX2009, 95:24-96:8). For example, adding the bulky, rigid barrel portion and guide plate of Zahiri to the leg 20 of Arnould would prevent the leg from bending rending it essentially non-functional. Additionally, including Zahiri's locking screw on top of the lag screw would require that leg 20 of Arnould be even larger and more prominently protruding from the surface of the bone plate. As compared to Zahiri, hole 25 of Arnould includes edge 25_2, which is described as "a concave surface" that permits the head of the screw "to rest and wedge against at least a portion of the edge 25_2, even if [the screw] axis 31 is inclined in relation to the axis 25_1 of the hole." (EX1006, ¶27).

Zahiri

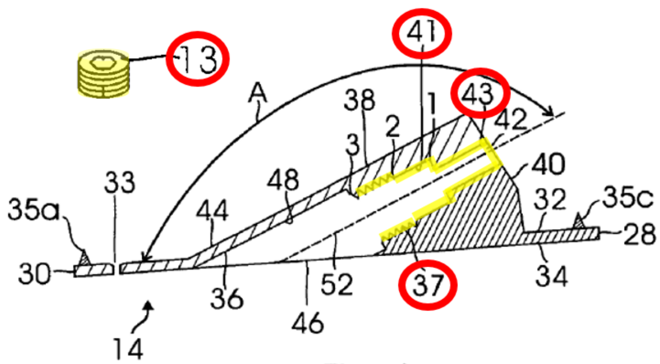
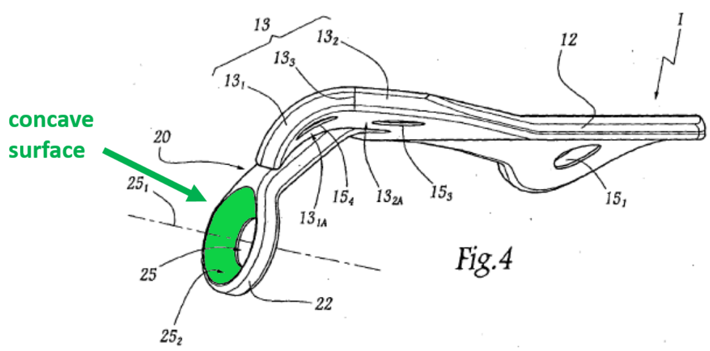


Fig. 4

Arnould



(EX1007, Fig. 4; EX1006, Fig. 4).

178. Mr. Sherman overlooks Arnould's disclosure that "[t]he plate 1 depicted is the most appropriate for the patient, particularly for the size of his metatarsal M and phalanx P." (EX1006, ¶12). Nowhere does Mr. Sherman discuss how the dimensions of Zahiri's odd angle internal fixation device "for use in a transverse fracture of a humerus" would be modified for a plate that is placed "on

the upper surfaces of the metatarsal and phalanx connected by the joint." (EX1007, Title; EX1006, ¶8). Thus, a POSITA would not have motivated reasonable expectation of success in combining Arnould and Zahiri in the manner set forth by Mr. Sherman.

4. Petitioner's Combination Is Based On Improper Hindsight

179. Further, Mr. Sherman purports to incorporate the temporary guide pins of Zahiri into Arnould's plate "to ensure correct placement." (EX1002, ¶¶194-196). Mr. Sherman relies solely on Zahiri and concedes that "Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted." (*Id.,* ¶194). This appears to be based on hindsight reasoning.

180. Regarding Zahiri, and as discussed above in Section XII.A, the "pin holes" and "four tips" of Zahiri were a specific improvement to the '055 patent and were included to prevent torquing, or spinning of the guide plate on the humeral cortex as the lag screw was advanced into the epiphysis. (EX2006, Fig. 3, EX1007, Fig. 3, 1:55-61, 3:41-44, 5:52-59). With the guide plate of the '055 patent having a smooth surface and being located on only one side of the fracture, additional fixation was required for Zahiri.

181. In my opinion, a POSITA would not have been motivated to combine Arnould and Zahiri because pre-existing screw holes of Arnould are used to position the bone plate prior to insertion of the long cross-screw, thereby eliminating the need

to incorporate the temporary fixation features of Zahiri. (*Id.*).

182. For example, Arnould's plate discloses that screw 2 is partially inserted into oblong hole 16 to "partially immobilize" the plate body 10 while the long cross-screw is inserted. Screw 2 is later "completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M." (EX1006, ¶¶31-33). Indeed, Arnould's disclosed method "for placing a metatarsal-phalangeal joint arthrodesis plate" requires, amongst other steps, first "[p]artially immobilizing the plate body on the metatarsal, allowing relative freedom of movement generally along the longitudinal direction of the plate body" and then "[p]ermanently immobilizing the plate body on the metatarsal and phalanx." (*Id.,* ¶8). Moreover, Arnould's plate is not at risk for the unwanted torquing or spinning of the guide plates disclosed in the '055 patent and Zahiri because Arnould is "partially immobilized" by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.*, ¶31). As such, a POSITA would understand that proper alignment is obtained in Arnould without the need for the separate "temporary guide pins used with pin holes" of Zahiri.[5] Therefore, a POSITA would

[5] Mr. Sherman selectively combines only the temporary guide pins used with pin holes of Zahiri with Arnould while failing to address or include the added fixation of the four tips of Zahiri. (Ex. 1002, ¶¶194-196). Adding the four tips of Zahiri to

not have been motivated to combine Zahiri with Arnould.

5. Multiple Embodiments Of Zahiri

183. Once again Mr. Sherman relies on different embodiments in Zahiri to show multiple claim limitations of the 713 patent. For example, Mr. Sherman provides annotations on Zahiri Figure 1 in connection with various elements of claim 32 (*see* EX1002, ¶¶221, 224), Figure 4 in connection with claim 33 (*see id.,* ¶229), Figures 3 and 8 in connection with claim 36 (*see id.,* ¶233), and Figure 8 in connection with claim 38 (*see id.,* ¶238). Zahiri, however, discloses that "the device 20 [shown in Figures 7 and 8] is different from that of 10 [shown in figures 1-4]. The difference includes the barrel portion and two additional screws." (EX1007, 8:32-34). Mr. Sherman confirmed that Zahiri discloses multiple embodiments. (EX2009, 88:24-89:3 ("Q. . . . Would you agree with me that the [Zahiri] figures depict several different embodiments? . . . A. I think that's correct.")). So at least for claims 36 and 38, Mr. Sherman relies on different embodiments of Zahiri without explaining why a POSITA would allegedly be motivated to combine such different embodiments and without explaining whether a POSITA would have had a reasonable expectation of success in making that combination.

Arnould's plate would not allow the plate body 10 to remain "displaceable in the direction 11 relative to the metatarsal M." (Ex. 1006, ¶¶31-33). This displacement is made possible by screw 2 and oblong hole 16 when the plate is temporarily fixed to the bones. (*Id.*).

184. For the reasons explained above, a POSITA would not have been motivated to combine Arnould and Zahiri. Thus, Arnould and Zahiri do not render obvious claims 32, 33, 36, 37, and 38.

B. Claim 32

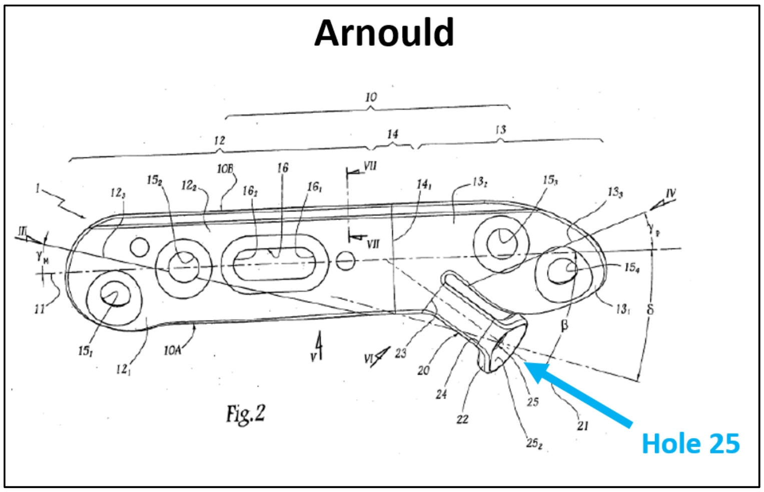
185. It is my opinion that Arnould and Zahiri do not render obvious claim 32 at least because they do not disclose claim element 32[f] which recites "the third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate." With respect to Arnould, Mr. Sherman opines that "the trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate. (δ)." (EX1002, ¶218). I disagree.

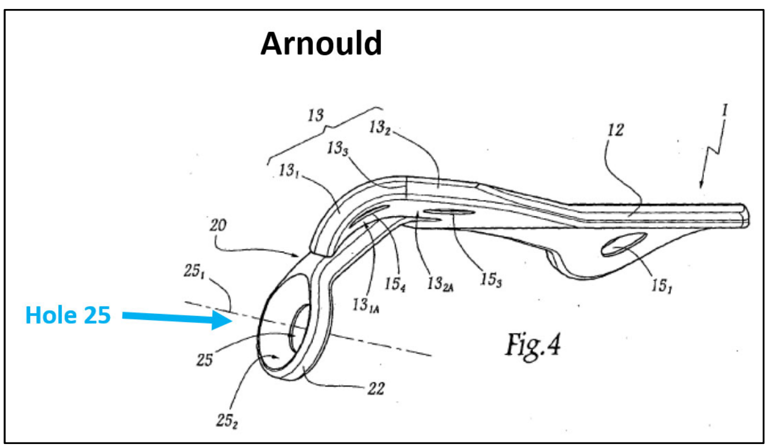
186. While the trajectory of screw 30 may be angled, it does not follow that hole 25 itself is necessarily angled. Rather, the size and shape of the screw head may permit the screw to be placed at different trajectories regardless of whether the hole is angled.

187. For example, a bone screw with a diameter smaller than the diameter of the hole may enable variable angles of fixation. Other factors such as the shape of the screw head and the material or geometric shape or design of the plate may also affect screw trajectory.

188. Angle β is formed by the longitudinal direction 11 and longitudinal direction 21 of leg 20, not hole 25. (EX1006, ¶25). Moreover, hole 25 is not an

"angled hole" as claimed. Rather, hole 25 appears to have the same shape and geometry of holes 15_1, 15_2, 15_3, and 15_4. (EX1006, Figs. 2, 4, 6). Hole 25 includes "a concave surface which is substantially complementary to an associated surface delimited by this screw head." (EX1006, ¶27). Hole 25 is not angled "through a thickness of the plate," as required by the claim. As can been seen in Figures 2, 4, and 6 below, holes 15_1, 15_2, 15_3, and 15_4 depict the same concave surface as 25_2 of hole 25 and the same circular shape as hole 25.





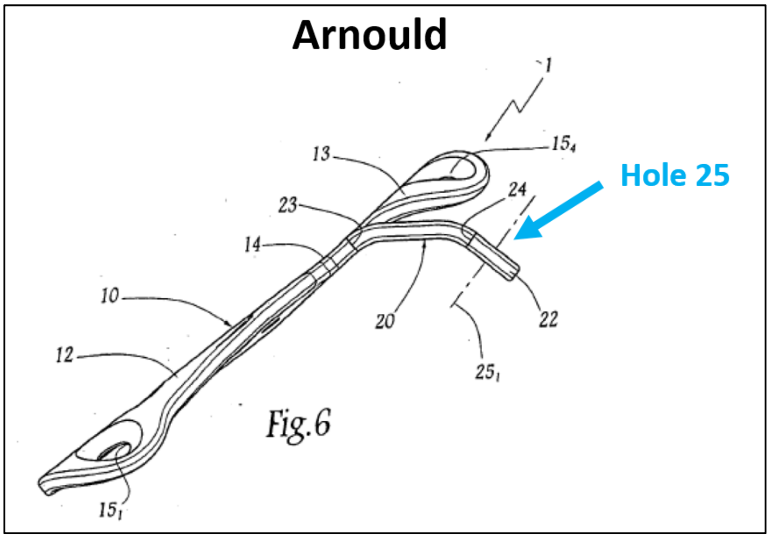


Fig.6

(EX1006, Fig. 2, Fig. 4, Fig. 6).

189. Before the Arnould plate is bent to contour to the metatarsophalangeal joint, Arnould describes that the plate "is manufactured from a flat metal plate." (*Id.* at ¶39). Aside of the chamfered edge (17), plate body 10, which includes holes 15_1, 15_2, 15_3, 15_4, and 25 disposed therein, has a uniform thickness. (*Id.*, *see also id.*, Fig. 7). Arnould nowhere states or shows that hole 25 is angled through the thickness of the plate.

190. Mr. Sherman also states that "[t]o the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to improve the integrity of the angled fixation screw, which includes putting the screw through a thickness of the plate." (EX1002, ¶221). First, as I explained above, a POSITA would not have been motivated to combine Arnould and Zahiri and Mr. Sherman provides no reasoning for such combination. (*see supra* at

Section XIII.A). As I explained above, a POSITA would understand that Arnould actually teaches away from Zahiri. (*Id.*). Specifically, Mr. Sherman provides no reasoning or justification for his statement that Zahiri could allegedly "improve the integrity of the angled fixation screw" of Arnould, much less does he provide any explanation of whether a POSITA would have a reasonable expectation of success in making such a combination.

191. For at least these reasons, Arnould and Zahiri do not render obvious claim 32.

C. Claim 33

192. For the same reasons set forth with respect to independent claim 32, it is my opinion that Arnould and Zahiri also do not render obvious claim 33.

D. Claim 36

193. Dependent claim 36 recites "the method of claim 32, wherein the plate includes a plurality of holes arranged according to the corners of a triangle or of a quadrilateral, and the method further comprises inserting fixation members into each of the plurality of holes so that some of the fixation members extend into the first bone while some of the fixation members extend into the second bone." Mr. Sherman states that this claim limitation is met by both Arnould and Zahiri. (EX1002, ¶¶232-234). I disagree.

194. As I explained above with respect to Ground 1, the 713 patent

plurality of holes so that at least one of the plurality of fixation members is angled with respect to another of the plurality of fixation members" as required by claim 37. For this additional reason, it is my opinion that Arnould and Zahiri do not render obvious claim 37.

F. Claim 38

202. Dependent claim 38 depends on claim 37, which depends on claim 36, which depends on claim 32. For the same reasons set forth with respect to claims 32, 36, and 37, it is my opinion that Arnould and Zahiri also do not render obvious claim 38.

203. Claim 38 includes the limitation "further comprising the step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone." Mr. Sherman concedes that "Arnould does not explicitly describe the use of k-wires to temporarily hold the plate in place while the screws are inserted." (EX1002, ¶240). Instead, Mr. Sherman asserts that the figures of Arnould "show pin holes that are used to temporarily secure the plate with k-wires during the implantation process." (*Id.*). But the holes that Mr. Sherman refers to are never discussed in Arnould.

204. As I explained above, a POSITA would not have been motivated to combine the temporary pins or pin holes of Zahiri with Arnould because (1) Zahiri is not a bone plate and therefore is not analogous art; and (2) Arnould teaches away

from Zahiri by providing its own procedure for immobilizing the plate during fixation. (EX1006, ¶31). Specifically, Arnould explains that "the surgeon inserts a screw 2 (Fig. 1) into the hole 16, on the side of the rear bottom 16_2 of this hole, without tightening the screw head against the edge of the hole. In this way, the plate body 10 remains displaceable in the direction 11 relative to the metatarsal M." (*Id.*). This technique described in Arnould negates the need for the temporary fixation of Zahiri.

205. For all of these reasons, it is my opinion that Arnould and Zahiri do not render obvious claim 38.

G. Claim 39

206. Dependent claim 39 depends on claim 32. For the same reasons set forth with respect to independent claim 32, it is my opinion that Arnould and Zahiri also do not render obvious claim 39.

XIV. GROUND 5: ARNOULD, ZAHIRI, AND MYERSON DO NOT RENDER OBVIOUS CLAIMS 34 AND 35

207. In my opinion, Arnould, Zahiri, and Myerson do not render obvious claims 34 and 35 of the 713 patent.

208. Claims 34 and 35 depend from claim 32. Mr. Sherman relies only on Arnould and Zahiri to meet claim 32. For the same reasons described above in Ground 4, it is my opinion that the combination of Arnould and Zahiri do not meet

the claim limitations of claim 32. Therefore, the combination of Arnould, Zahiri, and Myerson cannot render obvious claims 34 and 35.

A. A POSITA Would Not Have Been Motivated To Combine Arnould, Zahiri, and Myerson

209. Mr. Sherman offers the opinion that claims 34 and 35 are obvious in view of the combination of Arnould, Zahiri, and Myerson. (EX1002, ¶246). I disagree. Mr. Sherman's "Basis for the Combination of Arnould, Zahiri, and Myerson" and analysis of the challenged claims does not establish that a POSITA would have been motivated to combine Arnould, Zahiri, and Myerson.

210. Mr. Sherman summarily states that "[a] POSITA would be motivated to combine Arnould and Zahiri for at least the reasons set forth in Section IX.D.1." (*Id.,* ¶247). As I explained above, a POSITA would not be motivated to combine Arnould and Zahiri at least because they are not analogous art and because Arnould teaches away from Zahiri. (*see supra,* Section XIII.A).

211. Mr. Sherman further states that "Arnould describes the desire to completely secure the plate to the bone using the screws" and that "[i]n analogous art, Myerson discloses a bone plate for fusion of the MTP joint as well as for receiving a locking screw in combination with threaded holes to lock the fixation screws in place." (EX1002, ¶247). First, Mr. Sherman never explains why a POSITA would allegedly combine all three references (Arnould, Zahiri, and Myerson) together. Second, Mr. Sherman does not explain why a POSITA would think

Arnould's fixation purportedly needs to be improved. He further does not explain why a POSITA would select Myerson, out of all the available prior art, to achieve such alleged improvement.

212. For at least these reasons, it is my opinion that the combination of Arnould, Zahiri, and Myerson do not render obvious claims 34 and 35.

XV. CONCLUSION

213. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Digitally signed by Karl R. Leinsing
Date: 2022.11.18 13:44:13 -05'00'

Date: November 18, 2022

Karl R. Leinsing, MSME, PE

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

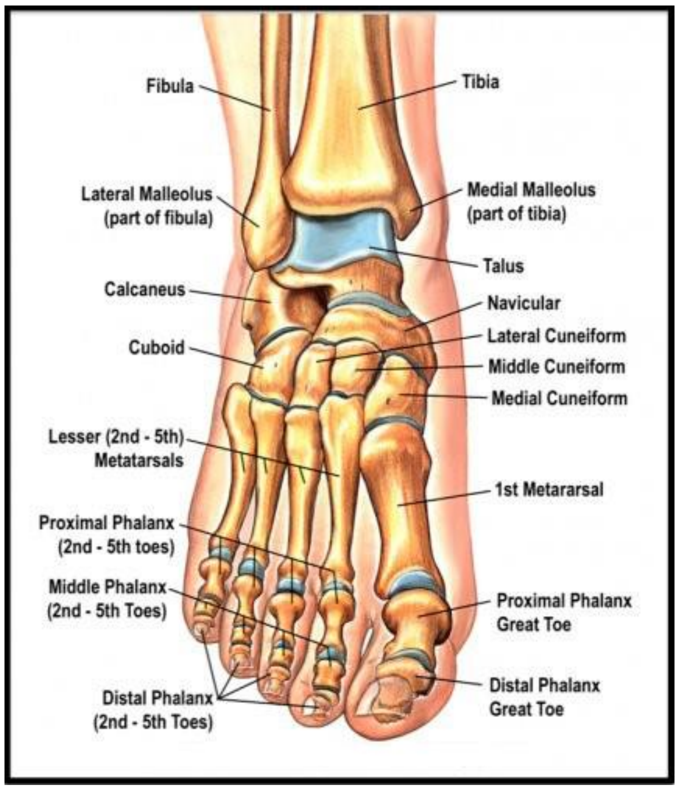
STRYKER EUROPEAN OPERATIONS HOLDINGS LLC ,
Patent Owner.

Case IPR2022-00487

U.S. Patent No. 9,078,713

DECLARATION OF DR. GEORGE B. HOLMES, JR., M.D., FAAOS
IN SUPPORT OF PATENT OWNER'S RESPONSE

25. The tarsal bones (shown below[1]) include the medial, intermediate, and lateral cuneiforms, the cuboid, and the navicular. The tarsal bones also include the calcaneus ("heel bone") and the talus. The tarsal bones form the transverse and longitudinal arch of the foot.



26. The metatarsophalangeal joints ("MTP joints") refer to the joints between the metatarsals and the proximal phalanx of each toe. A "first MTP joint"

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[1] Figure taken from www.FootEducation.com.

refers to the joint between the first metatarsal and the proximal phalanx of the great toe. The first MTP joint is a common area for arthritis ("hallux rigidus") and foot pain. Ambulation activities such as running and walking can cause cartilage in the first MTP joint to wear away over time.

27. The tarsometatarsal joints ("TMT joints") refer to the joints between the tarsals and the metatarsals.

28. The tibia (shown above) and fibula (shown above) are bones in the leg. The ankle is comprised of articulations between the distal tibia, the distal fibula, and the talus. The ankle joint is generally understood to be the tibiotalar joint, which is the joint between the tibia and the talus. The ankle joint connects the leg with the foot. The ankle joint allows up (dorsiflexion) and down (plantarflexion) movement of the foot.

29. The subtalar joint is the joint between the talus and the calcaneus. The subtalar joint allows for inversion and eversion of the foot.

30. Bone plates used in the foot are typically placed on the dorsal side of the foot because on the one hand it would be technically difficult to place a plate on the plantar surface while on the other hand such a plantar placement would lead to wound problems and painful walking (gait). The dorsum of the foot only has a thin layer of skin and subcutaneous tissue covering it. To accommodate the thin layer of

skin, bone plates used in the foot must have a low profile. Any abrupt protrusions would predispose the patient's skin, dorsal soft tissues, and tendons to tear or rupture and would also predispose the patient to develop wound complications and infection.

VI. SLATER

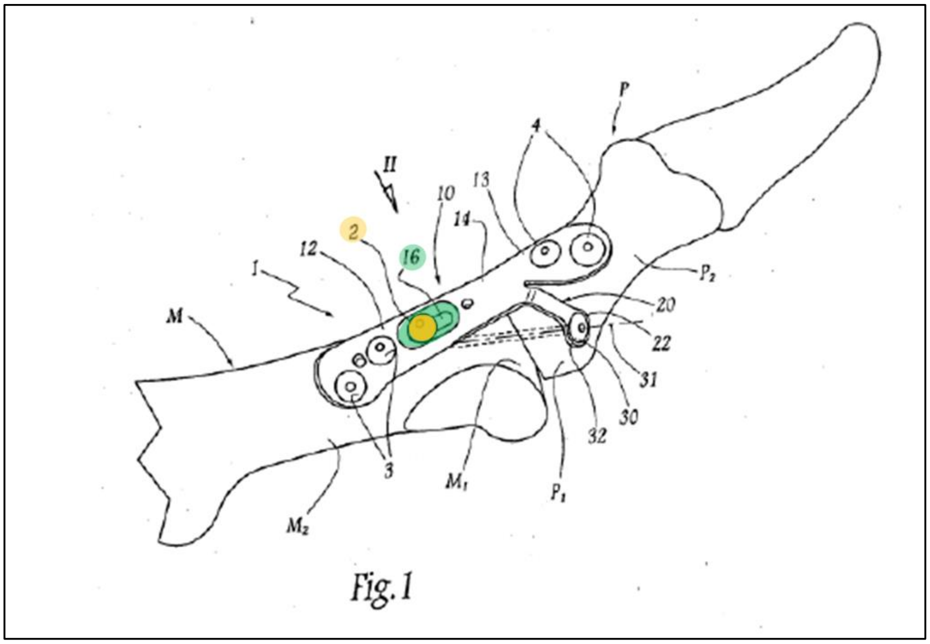
A. Elongated Openings 99 and 100 in Slater's Ankle Fusion Plate

31. Slater discloses a bone plate specifically designed for ankle fusion. In particular, Slater discloses "an ankle plate in which openings in the plate receive fixation screws allowing compression of bones being fused and orientation of the fixation screws to optimise accommodation of bone loading for efficient and effective fusion." (Ex. 1004 at 6:18-21). Prior to Slater, "the ankle [was] the only joint which to date does not have a specific plate for arthrodesis." (*Id.* at 6:3-4). Slater was developed based on the "long-felt want" for "a fusion plate that is effective and useful in primary ankle fusion and which will reduce or eliminate fusion failure rates and which provides appropriate geometry to facilitate integrity of the screw bone interface, screw insertion angle, screw tightness and effective cooperation between screw head and the screw insertion hole." (*Id.* at 6:4-9).

VII. ARNOULD

43. Arnould discloses a bone plate for fusion of an MTP joint. Specifically, Arnould "relates to an arthrodesis plate for a metatarsal-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe." (Ex. 1006 at ¶1). The Arnould plate features a leg that allows the plate to be attached to a dorsal-lateral surface of the epiphysis of the phalanx, where the bone is generally solid. (*Id.* at ¶3). The end of the leg includes a hole that receives a long screw that extends through the epiphyseal zone of the phalanx into the metatarsal epiphysis. (*Id.*).

44. Arnould discloses specific "surgical steps" that include, amongst others, "[p]artially immobilizing the plate body on the metatarsal, allowing relative freedom of movement generally along the longitudinal direction of the plate body" and "[p]ermanently immobilizing the plate body on the metatarsal and phalanx." (Ex. 1006 at ¶8). This partial immobilization, i.e., temporary fixation, is achieved with the use of oblong hole 16 and screw 2 shown below.



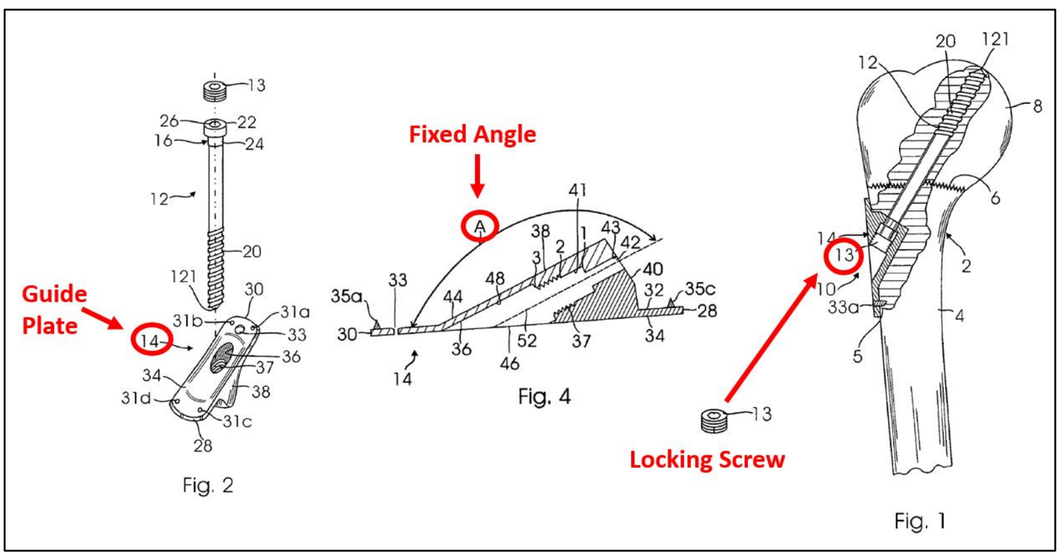
(Ex. 1006 at Fig. 1).

45. In particular, Arnould discloses that after the plate is placed across the metatarsophalangeal joint, "the plate body 10 is then partially immobilized using the oblong hole 16: the surgeon inserts a screw 2 (Fig. 1) into the hole 16, on the side of the rear bottom 16_2 of this hole, without tightening the screw head against the edge of the hole. In this way, the plate body 10 remains displaceable in the direction 11 relative to the metatarsal M." (*Id.* at ¶31). This displacement permits alignment adjustments of the plate. While screw 2 temporarily holds the plate over the joint, screw 30 is inserted to obtain compression between the proximal phalanx and the metatarsal. (*Id.* at ¶32). At this point, "screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the

metatarsal M." (*Id.* at ¶33). A POSITA would understand that using screw 2 in this manner serves to partially immobilize the Arnould plate across the metatarsophalangeal joint while the long screw is inserted through the hole in the leg 20 and screwed in, "bring[ing] the metatarsal M closer to the phalanx P, with this movement being guided along the direction 11 by the cooperation of the oblong hole 16 and the loose screw 2." (*Id.* at ¶32).

VIII. ZAHIRI

46. Zahiri describes a fixation device for both a transverse and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus. (Ex. 1007 at 2:16-20). The Zahiri device includes a barrel to guide a lag screw at a fixed angle across a proximal humeral fracture and to mate with a locking screw on the top of the lag screw once the lag screw is settled into the epiphysis. (*Id.* at Abstract).



47. In my opinion, Zahiri does not disclose a bone plate. Rather, Zahiri discloses a structural configuration for positioning a lag screw across a proximal humeral fracture. Zahiri does not incorporate a bone plate into its structural configuration.

48. Instead, Zahiri incorporates what it refers to as a "guide plate" into its structural configuration. The Zahiri "guide plate" functions as a washer by taking stress from the screw head and distributing the stress over the larger area of the "guide plate." The Zahiri "guide plate" also prevents the screw from impinging or migrating into the bone, and provides a structure in which a locking screw can be threaded to prevent loosening of the screw. However, a medical doctor would understand that the Zahiri "guide plate" does not and cannot provide any structural support to immobilize the bone fragments drawn into compression by the lag screw because, for example, it does not have the length or structural integrity of a bone plate.

49. Rather, the purpose of the structural configuration of the Zahiri device is to guide the insertion of the lag screw. (*Id.* at 3:26-31 ("It has additionally been discovered, according to the present invention, that with the aid of a newly designed hollow cylinder placed inside of the barrel of the guide plate, the guide plate can be further used to help make a guide hole on the bone for guiding the lag screw precisely

to settle into the bone at a desired angle.”)). In fact, Zahiri discloses “a procedure to make a guide hole for the lag screw 12.” (*Id.* at 6:49-50). Specifically, Zahiri explains that, in order to make the guide hole in the proximal humerus, the guide plate 14 and short barrel portion 38 are temporarily inverted so that “the backside 34 of the plate 14 contacts the bone cortex” and a drilling guide 15 can be “slidably inserted into the passage 52 of the short barrel 38.” (*Id.* at 6:50-64). Zahiri goes on to explain that “a long drill shaft from a conventional drill is inserted into the hole of the drilling guide 15” to make the guide hole at the “same angle as that of the barrel 38.” (*Id.* at 6:63-67). After the guide hole is created, the “guide plate 14 is removed” and “the newly created hole can host the barrel 38 portion of the guide plate 14” for insertion of the lag screw. (*Id.* at 7:4-9). In sum, the Zahiri device is “used to help make a guide hole on the bone for guiding the lag screw precisely to settle into the bone at a desired angle.” (*Id.* at 2:51-54). The ability to achieve a desired angle with such precision is a function of the engagement between the geometry of the barrel portion and the surfaces of the lag screw and the locking screw. (*Id.* at 6:12-35).

50. I understand that Mr. Sherman has opined that “[a] POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. A POSITA would know that bone plates

configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to the prior art inclusive of Zahiri when making improvements to Slater's bone plate." (Ex. 1002 at ¶164).

51. While I agree that some bone plates may be used for arthrodesis and for osteosynthesis, this is not true of every bone plate. Whether or not a bone plate can be used for arthrodesis and osteosynthesis depends on the particular characteristics of the bones being fixed. Such characteristics include, for example, the size of the bones and/or fracture to be fixed, their geometry, the quality of the bone, the amount and quality of soft tissue present, and the normal loads being placed on the bone(s).

52. As discussed above, Zahiri is not a bone plate. Zahiri discloses a structural configuration that includes a "guide plate" that is specifically designed for use with a corresponding lag screw for fixing fractures of the proximal humerus (typically a broken shoulder). A proximal humeral fracture refers to a break involving the area surrounding the humeral head, which is commonly known as the ball of the shoulder's ball and socket joint. Proximal humeral fractures are often the result of a patient with poor bone density (commonly elderly patients) falling onto an outstretched arm.

53. A POSITA would have understood that Slater's bone plate and Zahiri's

structural configuration cannot be used interchangeably because there are many practical differences between fusing an ankle joint and guiding a lag screw across a proximal humeral fracture. For example, the ankle joint is a hinge, weight-bearing joint with range of motion primarily confined to one plane (dorsiflexion and plantarflexion). The shoulder comprised of the proximal humerus is a ball and socket (rounded), non-weight-bearing joint that allows range of motion in multiple planes. In fact, the Zahiri device cannot be used for shoulder fusion. *See, e.g.,* Ex. 1002 at ¶39.

54. I understand that Mr. Sherman has opined that "[a] POSITA would understand that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate." (Ex. 1002 at ¶193).

55. While I agree that some bone plates may be used for arthrodesis and for osteosynthesis, this is not true of every bone plate for the reasons stated above. In particular, in my opinion, a POSITA would have understood that Arnould's bone plate and Zahiri's structural configuration cannot be used interchangeably because

there are many practical differences between fusing an MTP joint and guiding a lag screw across a proximal humeral fracture.

56. For example, the MTP joint is relatively flat but conical only allowing motion in one plane (the sagittal plane) whereas the proximal humerus is more rounded allowing motion in multiple planes. Therefore the fixation requirements are different due to the stark anatomical and biomechanical differences between fusing the MTP joint and fixing a proximal humeral fracture. As such, a POSITA would understand that Arnould's bone plate and Zahiri's structural configuration are not interchangeable.

IX. Combining Slater and Zahiri

57. I understand that Mr. Sherman opines that "a POSITA would look to . . . Zahiri when making improvements to Slater's bone plate." (Ex. 1002 at ¶164.) Mr. Sherman further opines that "a POSITA would be motivated to combine the teachings of Slater and Zahiri," (Ex. 1002 at ¶168), namely that "the temporary pin holes, as disclosed in Zahiri, could be implemented into Slater's bone plate to guide the plate alignment during implantation." (Ex. 1002 at ¶167.) I disagree that a POSITA would have been motivated to implement Zahiri's temporary guide pins and temporary pin holes into the Slater ankle fusion plate.

58. The Zahiri device is a small device designed to be positioned at the diaphyseal cortex of the proximal humerus. I understand that Zahiri's motivation

for including the specially designed pins for insertion into four pin holes, as well as the four tips, into the Zahiri structural configuration was to help stabilize the Zahiri plate during insertion of the lag screw. (Ex. 1007 at 1:50-61, 2:37-43).

59. In my opinion, a POSITA would not have been motivated to incorporate Zahiri's temporary pin holes into Slater's bone plate because—unlike Zahiri—Slater's bone plate (1) is designed to span the ankle joint, which is relatively flat; and (2) already includes multiple, pre-existing openings that can be used to stabilize the plate during insertion of the angled screw.

60. A POSITA would understand that partially inserting a screw into one of the elongated holes (openings 99 or 100) of the Slater plate serves to stabilize the plate prior to and during insertion of the angled screw. After the angled screw is inserted, the partially inserted screw can be fully inserted for permanent fixation. This process negates the need for any smaller temporary fixation pins or pin holes such as the ones used in the Zahiri device.

61. For a structural configuration like Zahiri that is used in the proximal humerus and is therefore more susceptible to unwanted torqueing or spinning, a surgeon understands that there is more of a need for temporary fixation members and tips than with bone plates used on the ankle or foot. In contrast, Slater's bone plate is not at risk for unwanted torqueing or spinning because of its size and shape

as well as the size and shape of the ankle joint. Without the temporary fixation pins and tips, the Zahiri device "is unstable in operation when the lag screw is pushed and turned to settle into the bone." (Ex. 1007, 1:51-57, 2:37-43). And unlike the ankle plate in Slater, which has multiple fixation screws on both sides of a bone discontinuity, for the guide plate in Zahiri, all fixation screws are on only one side of a bone discontinuity.

62. For at least these reasons, a POSITA would not have been motivated to combine the "temporary pin holes" of Zahiri with the plate of Slater.

X. Combining Arnould with Zahiri

63. I understand that Mr. Sherman opines that "a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement." (Ex. 1002 at ¶197). I disagree.

64. A POSITA would not be motivated to combine Zahiri's temporary guide pins and pin holes because the Arnould plate does not require the temporary fixation features of Zahiri. As explained above, Arnould expressly teaches that pre-existing screw 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate across the metatarsophalangeal joint while the long screw is inserted through the hole in the leg and across the MTP joint. The screw 2 is later "completely screwed and tightened into the hole 16 in order to completely

secure the plate body 10 to the metatarsal M." (Ex. 1006 at ¶¶8, 31-33).

65. Unlike Zahiri's structural configuration, the Arnould bone plate is not at risk for unwanted torqueing or spinning because of its size and shape as well as the size and shape of the MTP joint. Specifically, Arnould's bone plate is designed and contoured to span the MTP joint with fixation of the plate to the metatarsal and to the phalanx, with a leg portion configured to wrap around the phalangeal epiphysis. (Ex. 1006 at ¶23). Additionally, Arnould's bone plate avoids unwanted torqueing and spinning because, before inserting the cross screw 30 into hole 25, Arnould is "partially immobilized" by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.* at ¶31). In short, partial immobilization is achieved without the need for temporary fixation pins or pin holes.

66. As such, a POSITA would understand that the Arnould plate does not require the temporary fixation pins and pin holes of Zahiri. For at least these reasons, a POSITA would not have been motivated to combine Zahiri with the plate of Arnould.

XI. CONCLUSION

67. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

V.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner

Case IPR2022-00488
U.S. Patent No. 10,993,751

DEPOSITION OF MICHAEL SHERMAN
VIA VIDEOCONFERENCE

September 29, 2022

Reporter: John Arndt, CSR, CCR, RDR, CRR
CSR No. 084-004605
CCR No. 1186

A. The projection isn't, but the rest of the bottom (inaudible).
Q. So is it fair to say that the guide plate -- the guide plate portion of Zahiri is a bone plate?
A. Well, that -- again, I'm not -- you're asking me to provide opinions that I haven't provided in our reports. So I'm here to talk about our reports, and we're barely discussing them.
Q. Well, you relied on all these references; correct?
A. I did, but I didn't spend time thinking about whether Zahiri was two pieces or one piece or six pieces, for that matter. So Zahiri taught elements that can be combined with Slater and Arnould to render claim elements of Pondipass (ph) obvious, and that's what I'm here to talk about.
Q. And we'll get to your opinions. I'm just trying to understand what it is about prior art -- what you understand about the prior art, so we just have to sift through each of those references.
I want to look at the figures in Zahiri. There's a description of the figures in Column 4, and then the figures are obviously up front. Would you agree with me that the figures depict several different

embodiments?
MS. ALLOR: Object to the form.
A. I think that's correct.
BY MS. RATYCZ:
Q. For example, Figure 1 describes a 150 degree embodiment?
MS. ALLOR: Object to the form.
A. Well, I can read it. It says Figure 1 is a side elevation, a partial cross-section, one of the embodiments of the present invention -- fitted at two preferred angles, 150 degrees and 160 degrees, to fix a transverse fracture.
BY MS. RATYCZ:
Q. And you would agree with me that Figure 2 would be depicting the same embodiment as Figure 1?
A. Figure 2 is an enlarged, exploded perspective view of -- that's I guess the word I was missing -- of the present invention -- improved odd angle fixation device shown in the embodiment --
I don't have to agree with you, but that's what Zahiri says.
Q. And what about Figure 3? Is that the same as the embodiment described in Figures 1 and 2?
A. Figure 3 is a enlarged top perspective, yes, of the rectangular-shaped guide plate, the guide

Trials@uspto.gov
571-272-7822

Paper 20
Date: May 13, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01450 (Patent 8,529,608 B2)
IPR2021-01451 (Patent 9,351,776 B2)
IPR2021-01452 (Patent 9,763,716 B2)
IPR2021-01453 (Patent 10,245,085 B2)[1]

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

ORDER
Granting Petitioner's Motion to Submit Supplemental Information
37 C.F.R. § 42.123(a)

[1] We exercise our discretion to issue one Order to be filed in each case. The parties are not authorized to use this style of heading for subsequent papers.

IPR2019-01235, Paper 56 at 4 (PTAB Sept. 14, 2020) ("Petitioner has persuaded us that it would be prejudiced by introduction of [Patent Owner's] new evidence and arguments at this late stage of the proceeding because Petitioner would not have an opportunity to respond.").[3]

As the moving party, Petitioner must persuade us that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). Petitioner contends, with no dispute from Patent Owner, that it timely sought authorization to file this Motion. Mot. 3–4. We agree because Petitioner's request for authorization was made within 30 days of our institution decision. *See* Ex. 3001 (email from Petitioner's counsel dated April 5, 2022).

Petitioner further argues that the Sherman Declarations are relevant to the instituted claims of the '608 patent. Mot. 3–8. Petitioner contends that the declarations address the knowledge of a person of ordinary skill in the art ("POSA") "during the same time period for the same technological field" and address "the same prior art references (Slater and Arnould) with respect to similar claim limitations." *Id.* at 4. In both respects, Petitioner contends the Sherman Declarations contradict positions taken previously by Patent Owner related to the patentability of the '608 patent's claims, such as in Patent Owner's Preliminary Response. *Id.* at 4–8. We discuss in detail below.

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[3] In *Polycom*, the Board also considered the fact that Patent Owner had been aware and in possession of the supplemental information it sought to submit (certain standards documents) over a year before it filed its motion as evidenced by the filing of those documents in a related IPR between the same parties. *Polycom*, Paper 56 at 3–4.

Petitioner contends that the Sherman Declarations repeatedly opine that a POSA "would understand that ***there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture***" because "[a] [POSA] would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used ***interchangeably for decades***." *Id.* at 4–5 (quoting, with Petitioner's emphasis, Proposed Ex. 1022 ¶ 164). Petitioner argues this opinion is relevant to its challenge to the claims based on Falkner and Patent Owner's rebuttal thereto, which challenge cites Falkner's allegedly interrelated teachings about plates for spanning both fractures and joints. *Id.* at 5; Mot. Reply 2 ("The Sherman Declarations make it more probable that the cited disclosures of Falkner relate equally to joint fusion as they do fracture repair, as argued by Stryker and as supported by [Petitioner's declarant] Professor Gall."). According to Petitioner, the cited portions of the Sherman Declarations are also inconsistent with Patent Owner's earlier argument in this case, which "focused on alleged differences between fusing a joint and fixing a bone fracture." Mot. 4–5.

Moving to Slater and Arnould, Petitioner contends that the Sherman Declarations analyze those references, including the same embodiments addressed in Petitioner's challenge, when applying those references against similar claim limitations in the Stryker patents challenged by Patent Owner. *Id.* at 6–7. Petitioner cites opinion in the Sherman Declarations detailing Slater's teachings about a two-bone (tibia and talus) embodiment, which Patent Owner argued in the Preliminary Response was lacking in detail and did not meet the '608 patent's claim limitations requiring a plate for securing

two discrete bones together across a joint. *Id.* (citing, for example, Proposed Ex. 1022 ¶¶ 59, 76, 81); Mot. Reply 2 ("[T]he Sherman Declarations make it more probable that Slater contemplates use of the plate for the fusion of two bones."). For Arnould, Petitioner cites opinion in the Sherman Declarations that "Arnould ***clearly*** discloses ***a third hole located between said first hole and said second hole***," which testimony Petitioner contends supports its position that Arnould discloses a "transfixation screw hole disposed along the spine" as in the '608 patent's claims, and is allegedly inconsistent with Patent Owner's argument to the contrary in this case. Mot. 7 (citing Proposed Ex. 1023 ¶ 264 (with Petitioner's emphasis); Paper 5, 33–34); Mot. Reply 2–3.

Patent Owner responds that the Sherman Declarations are irrelevant. Opp. 1–5. Patent Owner contends that the Sherman Declarations do not address Falkner and that Petitioner's supplementation based on "the understanding of a [POSA] regarding bone plates is wholly irrelevant to an anticipation challenge." *Id.* at 2–3 (asserting that Petitioner is simply attempting to use the supplemental evidence to "backfill flaws" in the Petition). Patent Owner contends that there is no inconsistency in Patent Owner's positions about Slater. *Id.* at 3–4. According to Patent Owner, it has acknowledged that Slater discloses a two-bone embodiment and the Sherman Declarations rely on Slater as part of an obviousness theory, not anticipation. *Id.* (asserting that Petitioner's proposed supplementation "potentially even asks this Board to modify its Slater grounds to be obviousness"). As for Arnould, Patent Owner contends that a screw hole located "between" two other holes is not the same thing as a transfixation

screw hole being disposed along a plate's spine as recited in claims of the '608 patent. *Id.* at 5 (noting differences in claim scope in the respective patents and that "[t]he concept that a hole be located between two holes is broader than the requirement here that the transfixation screw hole be disposed in a particular area of the plate."). Thus, Patent Owner argues, there is no inconsistency in its positions on Arnould. *Id.*

Patent Owner further argues that Petitioner's motion lacks specificity about how Petitioner intends to use the supplemental information. Opp. 6. Patent Owner contends none of Petitioner's cited authority allowed supplementing the record with testimony from a different expert, and that Mr. Sherman will not be testifying as an expert on Patent Owner's behalf in this proceeding. *Id.* at 6–7. Lastly, Patent Owner contends it will be prejudiced if the Motion is granted. *Id.* at 7–8.

Petitioner persuades us that the Sherman Declarations are relevant to claims for which trial has been instituted here. Patent Owner is correct that the Sherman Declarations do not analyze the Falkner reference, but Patent Owner's argument that Mr. Sherman's opinion on the perspective of a POSA being wholly irrelevant to Petitioner's anticipation challenge is overstated. The POSA's background knowledge and perspective is important even when anticipation is the issue. *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) ("A reference anticipates a claim if it discloses the claimed invention 'such that a skilled artisan could take its teachings *in combination with his own knowledge of the particular art and be in possession of the invention*.'" (quoting *In re LeGrice*, 301 F.2d 929, 936 (CCPA 1962))). Mr. Sherman's opinion about the lack of differences

between fixing fractures and fusing bones across a joint appears to reflect the POSA's understanding at about same time that the '608 patent was filed, in the same general subject matter as the '608 patent. In at least that respect, the Sherman Declarations are relevant to the instituted claims and Petitioner's theory that a POSA would understand Falkner's teachings as applying to bone plates usable for spanning a joint or fixing a fracture. We do not presently see this supplementation as Petitioner trying to change its theory from anticipation to obviousness, nor will we permit Petitioner to do so—the Petition asserts that Falkner anticipates the claims, and Petitioner is bound by that theory.

The cited testimony about Slater in the Sherman Declarations is also relevant to the instituted claims here. That testimony is, at minimum, relevant to a POSA's understanding of Slater's disclosure of an embodiment where the plate is attached to only the tibia and talus, and to the sufficiency of that disclosure. Whether Mr. Sherman's testimony is inconsistent with Patent Owner's past argument on Slater is not something we must decide at this time or for this Motion.[4] What is important at this time, as discussed above, is that the testimony tends to support—and, thus, is relevant to—Petitioner's and Dr. Gall's position in the Petition that Slater discloses an embodiment where two (and only two) bones are involved in the fusion.

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[4] Although Patent Owner contends it never denied that Slater includes a two-bone embodiment, Patent Owner also argued that Slater did not disclose claim 1's preamble of a "system for securing two bones together across a joint between the two bones." Paper 5, 11–14. Inconsistent or not, it is difficult to reconcile this aspect of Patent Owner's argument with Patent Owner's apparent admission about a two-bone embodiment in Slater.

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioners,

v.

OSTEOMED LLC,
Patent Owner.

Case IPR2021-01450
U.S. Patent No. 8,529,608

DECLARATION OF MARK SOMMERS, MS

bone, through the screw into said head and said bridge portion." I discuss each of these insufficiencies in more detail below.

a. Disposed Along the Spine

162. First, I disagree with Dr. Gall's assessment that *Arnould* includes "a transfixation screw hole disposed along the spine." The elongate spine of *Arnould* is the portion of the plate I have identified in blue, below. The transfixation screw hole that Dr. Gall identifies is not along this blue spine, but instead on a narrow leg portion (identified in red) that juts out from the side of the elongate spine of *Arnould*.

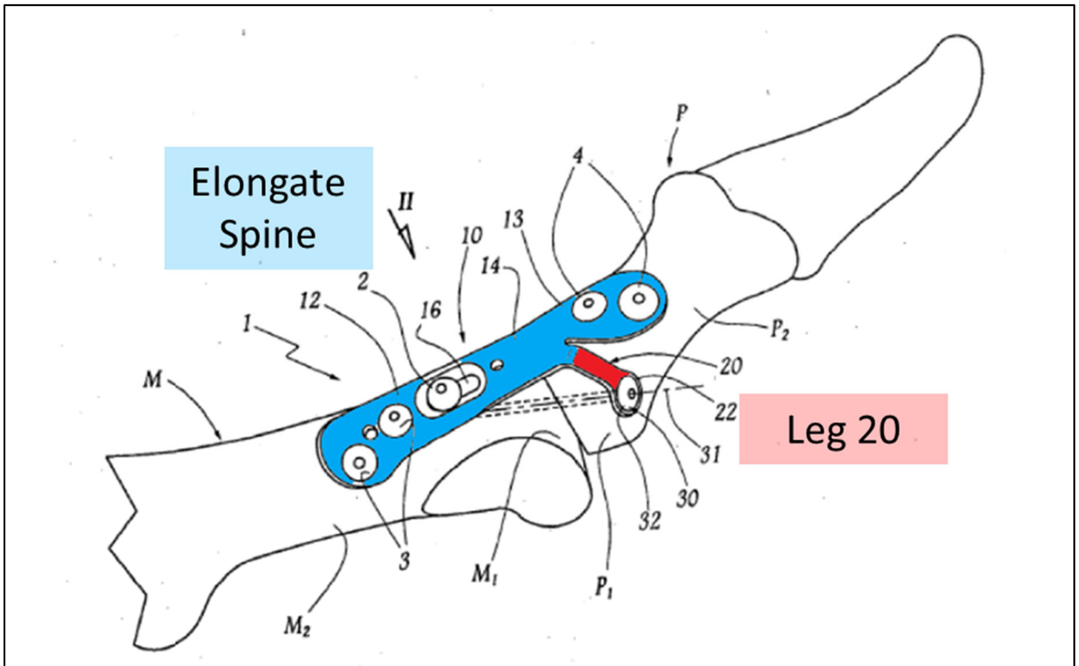

Fig. 1

(Ex. 1008, Fig. 1 (annotated); *id.*, ¶ [0027]).

163. In my opinion, "disposed along the spine" refers to being placed in the blue portion that I identify in the figure above, i.e., on or in the spine. *Arnould* describes the red leg as an extension from the elongate spine of the plate itself: "[t]he leg 20, which is also located on the inner longitudinal side 10A of the plate body 10, **extends** lengthwise from the phalangeal portion 13." (Ex. 1008, ¶ [0023] (emphasis added)).

164. In additional discussion regarding the leg 20, *Arnould* explains that it "gives the impression of **plunging downward in relation to the plate body 10** . . ." (Ex. 1008, ¶ [0023] (emphasis added)).

165. Moreover, a POSITA would not alter *Arnould* to move the transfixation hole to be disposed along the spine because the explicit advantage of *Arnould* is that the leg and long screw were moved off the spine to generate "a significantly higher capacity to resist bending stresses than the plate body due to its structure and **implantation zone**." (Ex. 1008, ¶ [0006] (emphasis added)).

166. Thus, for the reasons above, *Arnould* in view of *Slater* fails to disclose "a transfixation screw hole disposed along the spine." Therefore, in my opinion, *Arnould* in view of *Slater* does not render obvious claim 1 of the '608 Patent. This claim element is also present in claim 11 of the '608 Patent and therefore

Arnould in view of *Slater* does not render obvious claim 11 of the ’608 Patent, either.

b. Transfixation Screw Extends Through the Bridge

167. I disagree with Dr. Gall’s assessment that *Arnould* in view of *Slater* teaches “the transfixation screw extends through the bridge portion,” as required in claim 1 of the ’608 Patent.

168. As detailed above, Dr. Gall identifies “junction zone 14” as the bridge portion of the *Arnould* plate. This junction zone is illustrated below.

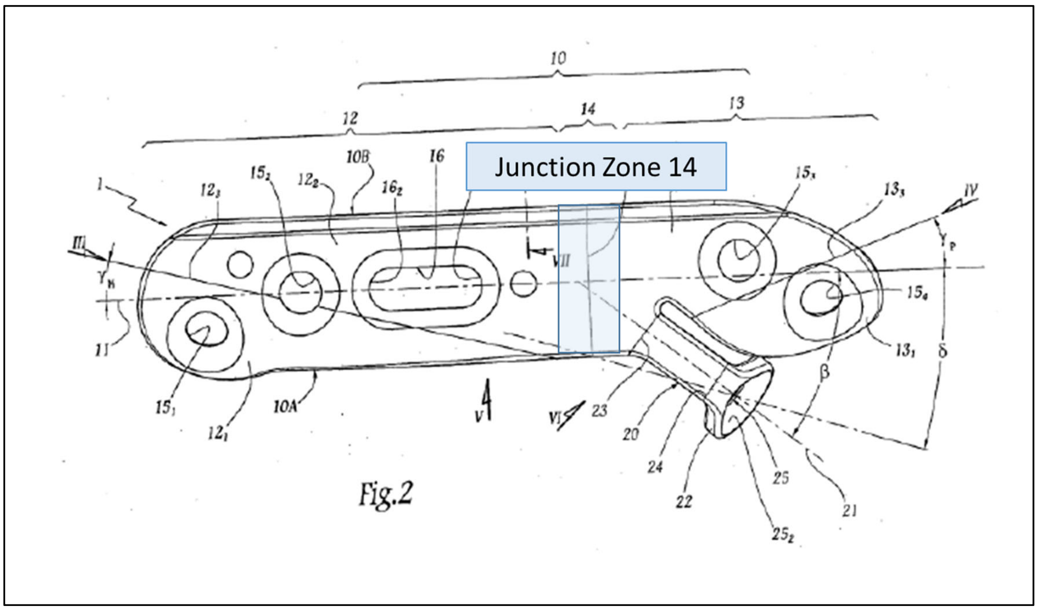

Fig.2

(Ex. 1008, Fig. 2 (annotated)).

169. As is apparent from Figure 2 of *Arnould*, the transfixation screw does not extend through the junction zone 14, but rather extends through the hole 25

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00488
U.S. PATENT NO. 10,993,751

PETITION FOR *INTER PARTES* REVIEW

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Alexandria, VA 22313-1450

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VI. CLAIM CONSTRUCTION

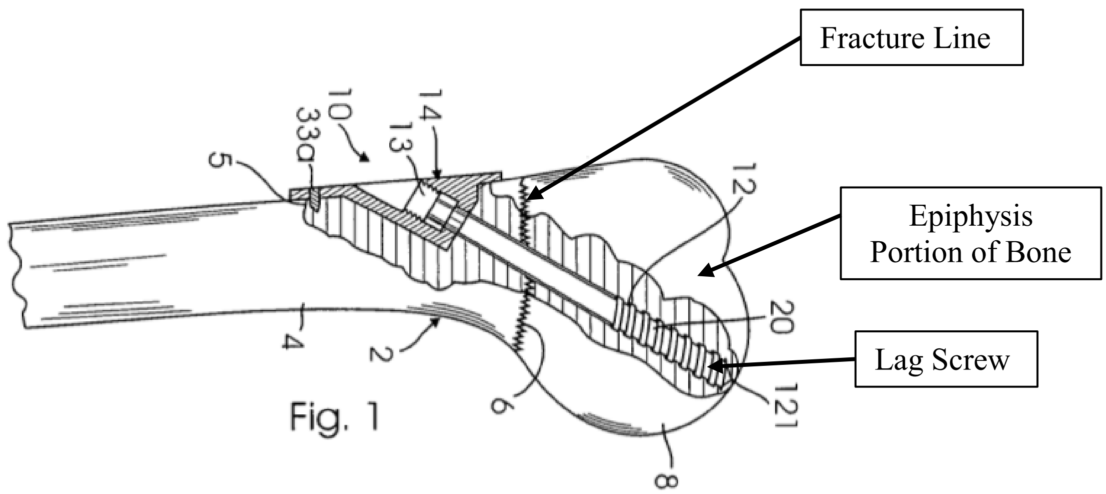
For purposes of this proceeding, no terms need to be construed as the prior art because under any construction of the terms of the Challenged Claims, the claims are unpatentable. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Petitioner reserves its right to respond to any unforeseeable claim constructions Patent Owner may advance. (Ex. 1002, ¶¶22-26).

VII. STATEMENT OF PRECISE RELIEF REQUEST AND REASONS THEREFORE

Petitioner requests the institution of IPR and cancellation of the Challenged Claims as follows:

Ground	Basis	Relied-On References	Claim(s)
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater ("Slater") (Ex. 1004)	1, 2, 7, 8
2	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	1-2, 7-18
3	§103	Slater, Zahiri, and U.S. Pat. Pub. No. 2006/0241592 to Myerson ("Myerson") (Ex. 1010)	6
4	§103	E.P. Patent No. 1,897,509 to Arnould ("Arnould") (Ex. 1005-1006) and Zahiri	1-3, 7-18
5	§103	Arnould, Zahiri, and Myerson	6

a fourth hole that is defined by an opening side wall 43 that extends from a first point 1 to an opening 42. (*Id.*; Ex. 1002, ¶169). Zahiri discloses the lag screw advances/traverses across the fracture line at an angle and settles into the depth of the epiphysis of the bone:



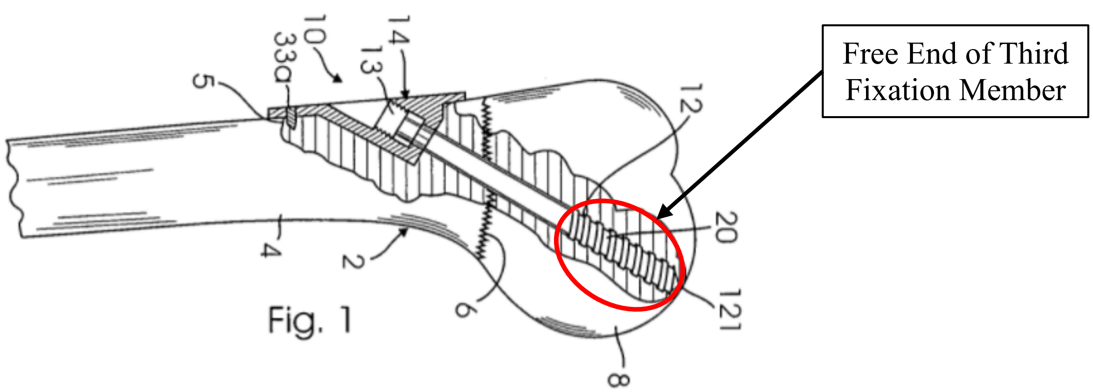
(Ex. 1007, FIG. 1 (annotated); 2:23-28; Ex. 1002, ¶170). A POSITA would readily combine the disclosure of the lag screw from Zahiri, which utilizes the third and fourth holes, into the plate of Slater, to further improve the integrity of the angled fixation screw of Slater's bone plate. (Ex. 1002, ¶¶171-172).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶173).

x. <u>[11i] wherein a free end…</u>

While Slater discloses the use of a third fixation member that has a free end not attached to any portion of the bone plate and resides in the second discrete bone

(Section VII.C.2.a.viii (citing Ex. 1004, FIG. 1, 11:19-25)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶174). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*). Zahiri's bone plate comprises a lag screw that is inserted through barrel portion of the bone plate and settles into the depth of the epiphysis portion of the bone:

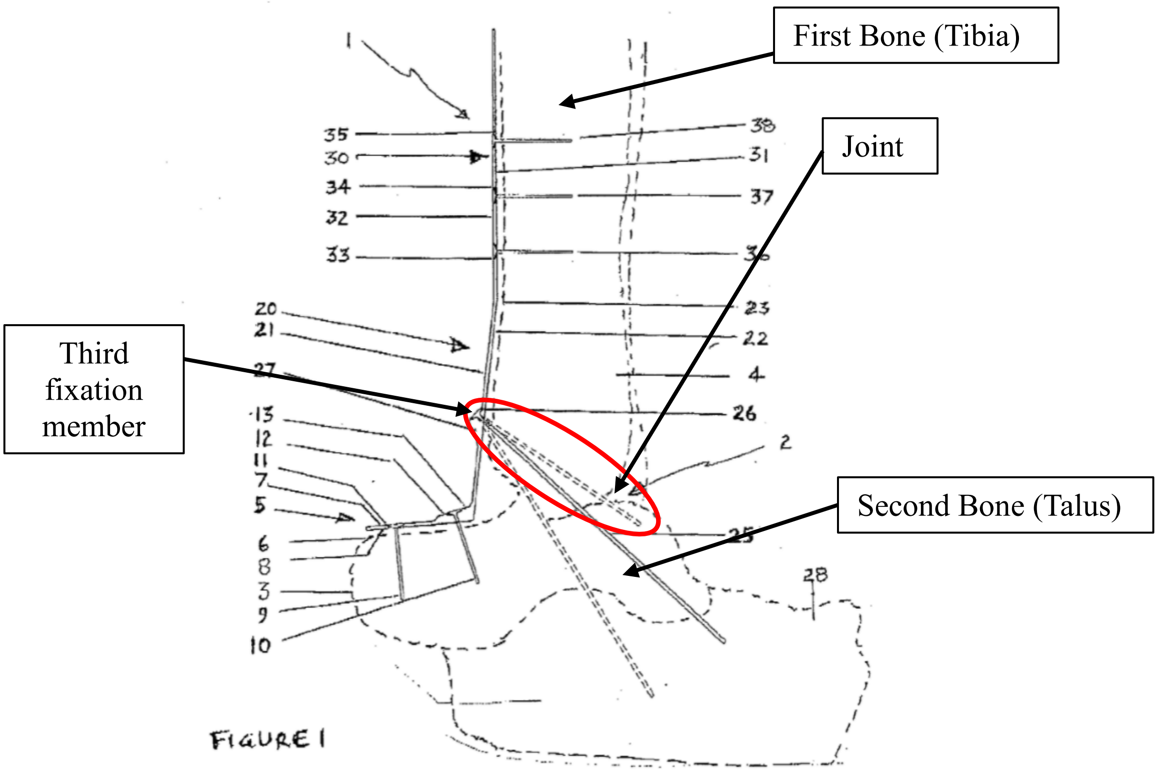


(Ex. 1007, FIG. 1 (annotated); 2:23-28, 5:5-8). A POSITA would understand that the distal threaded position 20 of the lag screw 12 does not attach to any portion of the bone plate. (Ex. 1002, ¶¶175-176). As with element [11h], a POSITA would have been motivated to combine the teachings of Zahiri regarding the third fixation member with Slater's bone plate. (Section VII.D.2.b.ix).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶177).

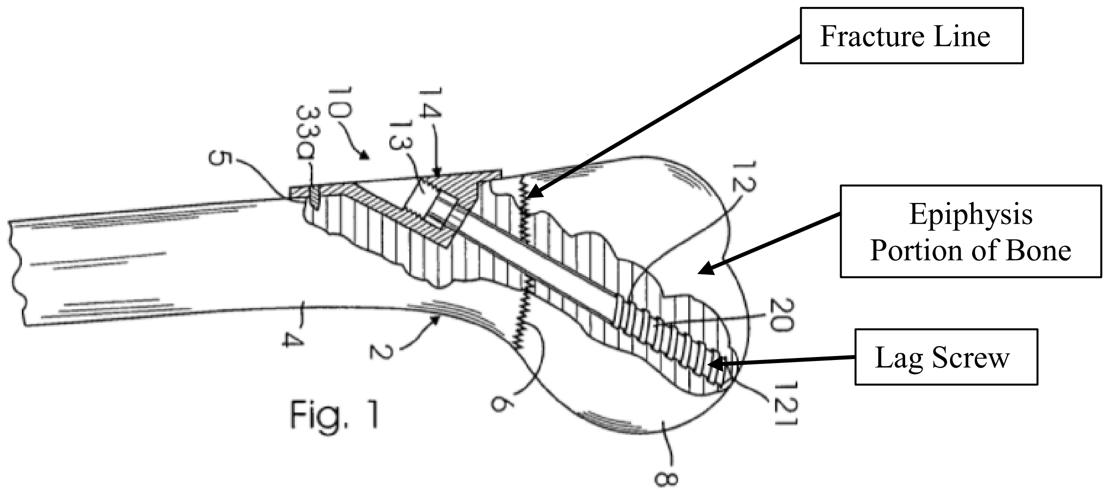
xi. [11j] and wherein the third fixation member…

Slater discloses the use of a third fixation member that is the only fixation member extending across the joint:



(Ex. 1004, FIG. 1 (annotated); 11:19-25). While it appears there is depth to opening 26 in formation 27 to allow for the screw head (third fixation member) to be countersunk, or seated below the plate (*, e.g.*, Ex. 1004, FIG. 1, 12:23-25), Slater lacks sufficient disclosure of the full dimensions of the third fixation member. (Ex. 1002, ¶¶178-179). A POSITA would look to prior art like Zahiri for disclosure of a fixation member with a fixation head defining a head area, the head area being greater than the second area and less than the first area. (*Id.*).

Zahiri discloses a lag screw that traverses across the fracture line at an angle and settles into the epiphysis of the bone:



(Ex. 1007, FIG. 1 (annotated); 2:23-28). A POSITA would understand that the fixation member anchors to the epiphyseal zone of the second bone and teaches the limitations of the third fixation member. (Ex. 1002, ¶¶180). It would be obvious to a POSITA that Slater depicts a free end of bone screw 25 configured to reside deep within the talus (the second bone). (*Id.*). As with element [11h], a POSITA would have been motivated to combine the teachings of Zahiri regarding the third fixation member with Slater's bone plate. (Section VII.D.2.b.ix; Ex. 1002, ¶181).

A POSITA would find this element obvious in view of Slater and Zahiri. (Ex. 1002, ¶182).

xii. <u>[11k] and a temporary fixation member…</u>

The purpose of the fifth hole is to receive a temporary fixation member. Slater

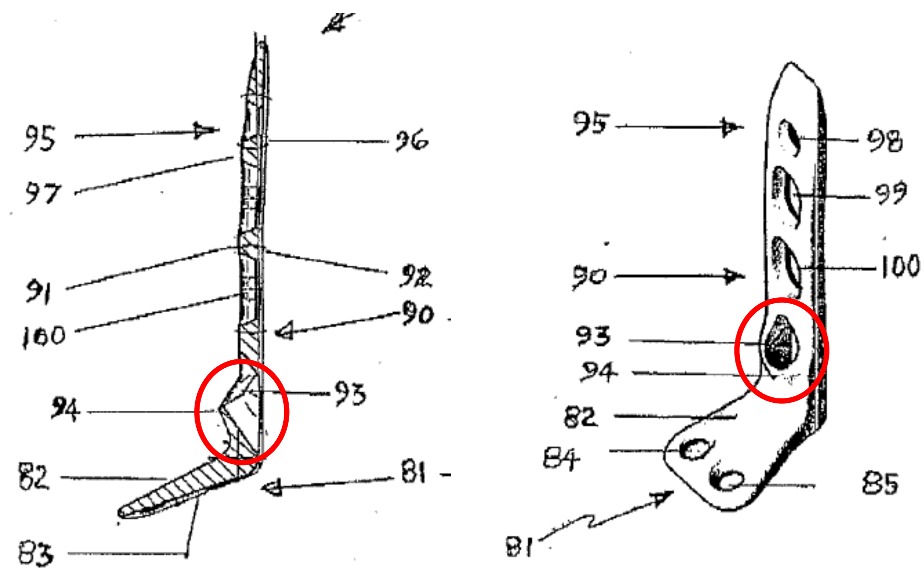
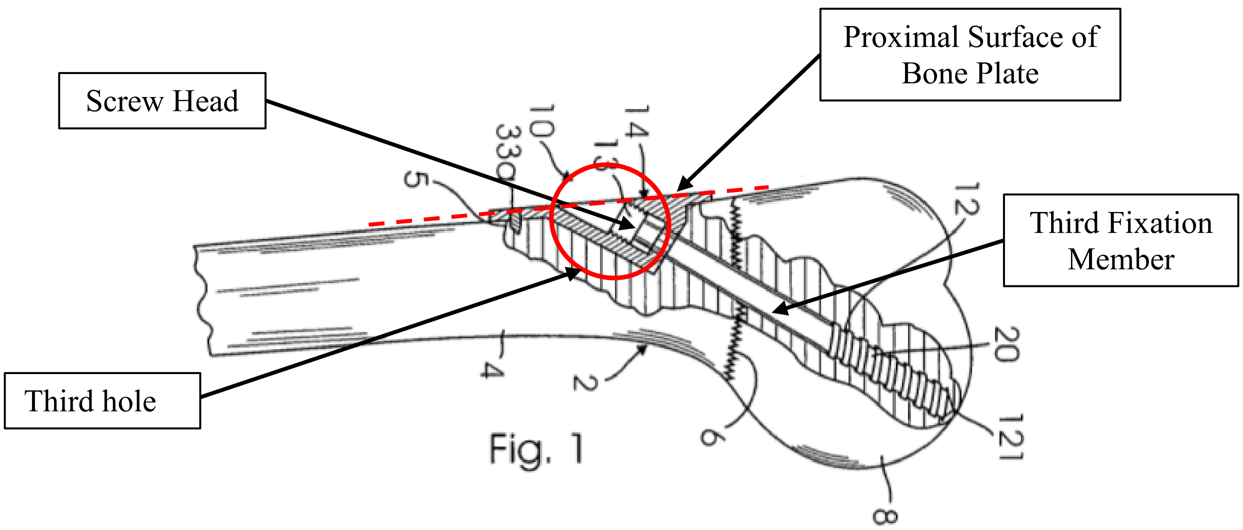


FIGURE 5 FIGURE 7

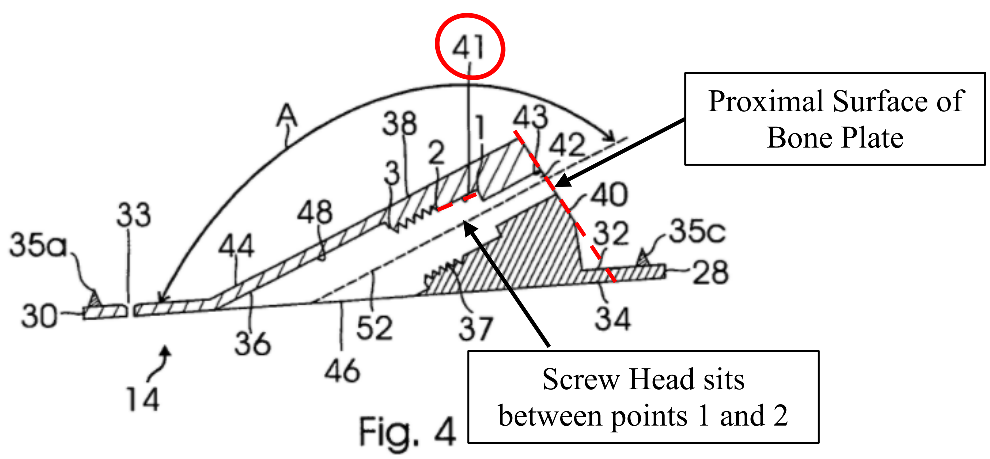
(Ex. 1004, FIGS. 5, 7 (annotated); 13:21-24 ("Disposed in portion 90 is a fixation screw which passes through opening 93 in formation 94. Formation 94 is configured so that a fixation screw is directed at an angle within a predetermined allowable angular range.").

A POSITA would find this element disclosed by Slater. (Ex. 1002, ¶204-208).

A POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶209). Zahiri discloses a lag screw 20 that crosses a fracture line with a head that engages with the threaded wall of the short barrel portion 38 of the bone plate 14:



(Ex. 1007, FIG. 1 (annotated); 2:23-36, 7:31-38). Zahiri further show that inner cylinder wall 41 "has a length defined between the first point 1 and the second point 2, which is the same as the height of the proximal head of 22 of the lag screw":



(Ex. 1007, FIG. 4 (annotated), 6:21-24). Since the screw head sits between points 1 and 2, which are below the surface of the bone plate, Zahiri expressly contemplates this limitation.

F. Ground 4: Claims 1-3 and 7-18 are Unpatentable Under 35 U.S.C. §103(a) as Obvious over Arnould and Zahiri

Independent claims 1, 11, and 17, and dependent claims 2-3, 7-10, 12-16, and 18, are obvious in view of the combination of Arnould and Zahiri. (Ex. 1002, ¶243).

1. Basis for the Combination of Arnould and Zahiri

The scope and content of the prior art includes Arnould and Zahiri, which collectively disclose all of the elements of claims 1-3 and 7-18. There are no differences between the subject matter of these claims and the combination of Arnould and Zahiri. (Ex. 1002, ¶244).

Arnould and Zahiri disclose bone plates with diagonal fixation members configured to compress the intersection of a first and second bone, in analogous fields of invention. (Ex. 1006, ¶6; Ex. 1007, 2:20-31). Arnould's bone plate comprises a hole 25 that determines the relative position of a screw 30 that passes through and fuses the joint between the metatarsal and phalanx (also known as the phalanges). (Ex. 1006, ¶31). Arnould explains that "the screw works mainly by means of traction." (Ex. 1006, ¶6). A POSITA knows that screws positioned across an interface, "working in traction" are providing compression at the interface. (Ex. 1002, ¶¶245-246). Arnould further discloses a variable fixation angle between the longitudinal axis of the plate body, selected by the surgeon to fuse the metatarsal and phalanx. (Ex. 1006, ¶¶27, 32). Arnould teaches that the surgeon "has the possibility

of modifying the angle α," indicating the surgeon can choose the angle at which the fixation member is inserted to achieve an optimal interface between the screw and the bone. (Ex. 1006, ¶38; Ex. 1002, ¶247). It may be argued that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate.

Arnould's disclosure at least guides a POSITA to incorporate the teachings of Zahiri, and position the third hole at an angle relative to the longitudinal thickness of the bone plate. (Ex. 1002, ¶248). Zahiri's bone plate fuses a first and second bone part with an angled fixation member and compresses the bone fracture:

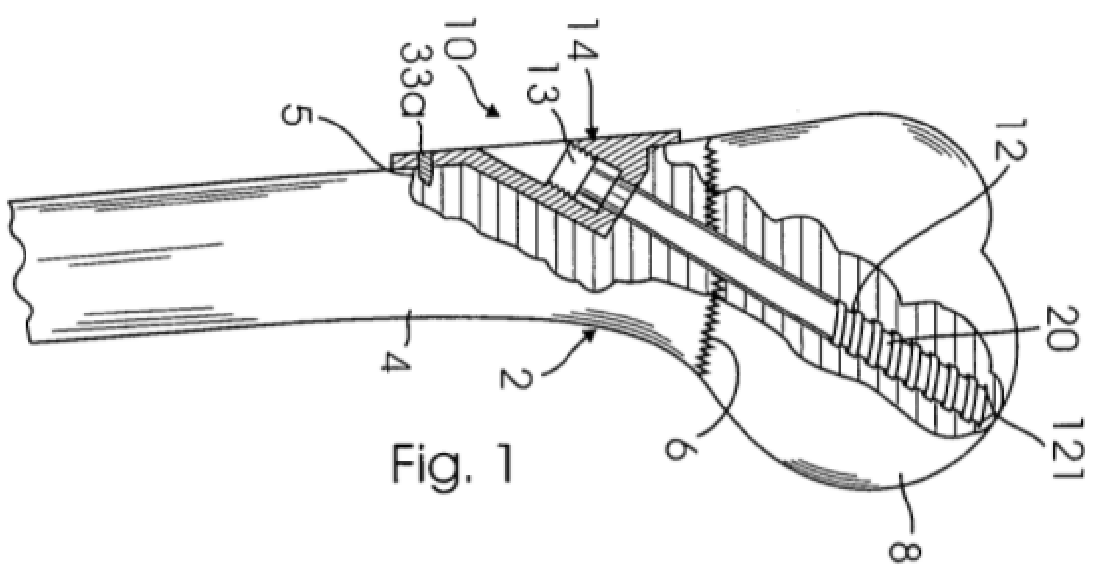


Fig. 1

(Ex. 1007, FIG. 1; 2:23-28). Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bones while dissipating the force along the plate so it does not damage the bones. (Ex. 1007, 5:65-6-11). A POSITA would understand that there are no practical differences between stabilizing

a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose fusing a bone fracture. (Ex. 1002, ¶249). A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. (*Id.*). A POSITA would look to Zahiri when making improvements to the plate disclosed in Arnould. (*Id.*).

Arnould discloses a method for partially affixing the bone plate to the bone by partially immobilizing the plate using a screw that is not tightened fully in an oblong hole so that the surgeon can correctly position and align the plate. (Ex. 1006, ¶31; Ex. 1002, ¶250). Arnould discusses the difficultly of proper plate alignment faced by the surgeon during implantation and the importance that proper placement has on patients' comfort. (Ex. 1006, ¶3). A POSITA would understand that Figure 2 of Arnould illustrates temporary guide holes (circled in red below) that are used to temporarily secure the plate during the implantation process:

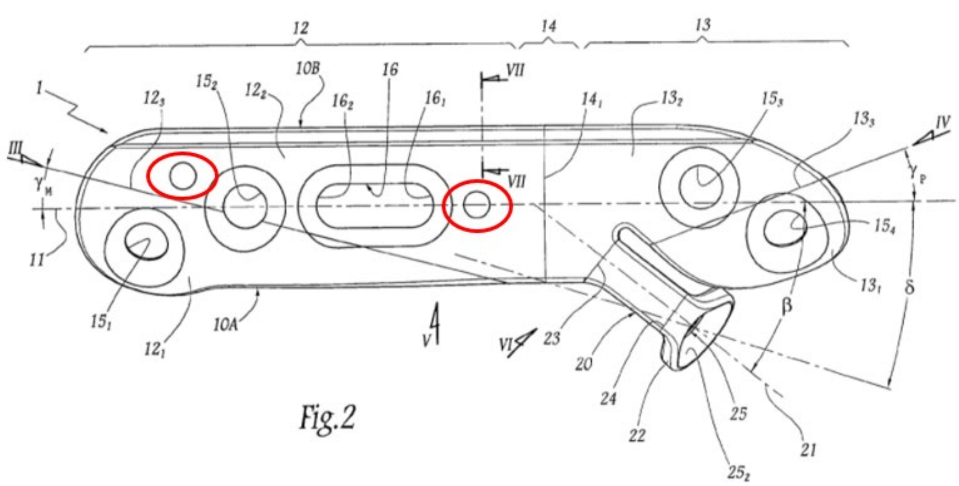


Fig.2

(Ex. 1006, FIG. 2 (annotated); ¶31; Ex. 1002, ¶251). While the figures of Arnould show such temporary guide holes, Arnould lacks sufficient disclosure regarding temporary fixation members in the guide holes. (Ex. 1002, ¶252). A POSITA would look to prior art in the relevant field, like Zahiri, for this disclosure. (*Id.*).

Zahiri discusses the importance of plate alignment and discloses an improvement that uses temporary locking pins to temporarily secure the bone plate to the bone. (Ex. 1007, 3:11-18). Zahiri discloses four small holes in the corner of the bone plate that temporarily hold the bone plate in place during implantation:

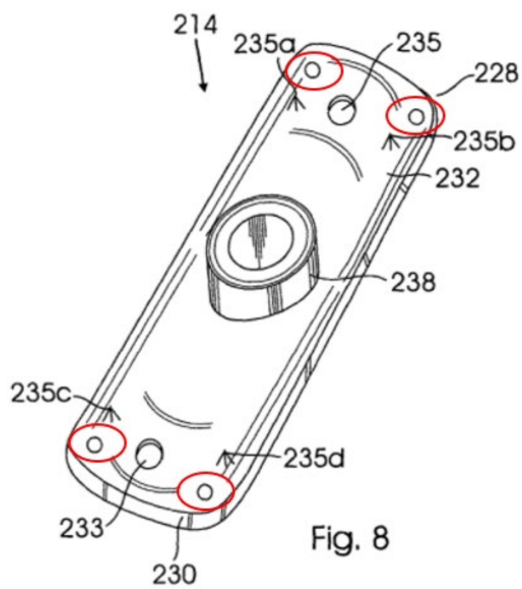


Fig. 8

(Ex. 1007, FIG. 8 (annotated); 3:11-18 ("[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location.")). The four small holes

are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (*Id.*). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (Ex. 1007, 3:11-18, 7:19-24, 7:63-66; Ex. 1002, ¶¶253-254).

As the use of these temporary guide pins would be before the plate is permanently affixed, a POSITA would look to incorporate these improvements disclosed by Zahiri into Arnould to ensure correct placement. (Ex. 1006, ¶¶3, 31; Ex. 1002, ¶¶255). A POSITA would understand that the temporary guide pins used with pin holes, as disclosed in Zahiri, could be implemented with Arnould's bone plate to temporarily secure the plate alignment during implantation. (Ex. 1002, ¶255). A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins, rendering the incorporation of Zahiri's temporary guide pins obvious. (Ex. 1006, FIG. 1; Ex. 1002, ¶255). Zahiri discloses a known technique for improving plate alignment during implantation. (Ex. 1002, ¶255).

A POSITA would be motivated to combine the teachings of Arnould and Zahiri, to utilize a known technique for improving the implantation of a bone plate (similar device), and obtain a similar improvement. (Ex. 1002, ¶256).

2. Claims 1-3, 7-10, 12-18 are Obvious

a. *Independent Claim 1*

i. [1Pre]

Arnould discloses a bone plate configured for arthrodesis of a joint between the first metatarsal and the first phalanx. (Ex. 1006, ¶11 ("Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot.")).

Arnould discloses this element. (Ex. 1002, ¶257).

ii. [1a]

Arnould's bone plate 1 comprises a plate body 10 that "includes, along its longitudinal direction 11, a metatarsal portion 12 [a second end] and a phalangeal portion 13 [a first end] which are respectively adapted to be placed and fixed on the metatarsal M and the phalanx P." (Ex. 1006, ¶14).

Arnould discloses this element. (Ex. 1002, ¶¶258).

iii. [1b]

Arnould's bone plate comprises holes 15_3 and 15_4 (first hole(s)) configured to attach to the phalangeal portion 13 (first end) of the plate 1 to the phalanx (first bone):

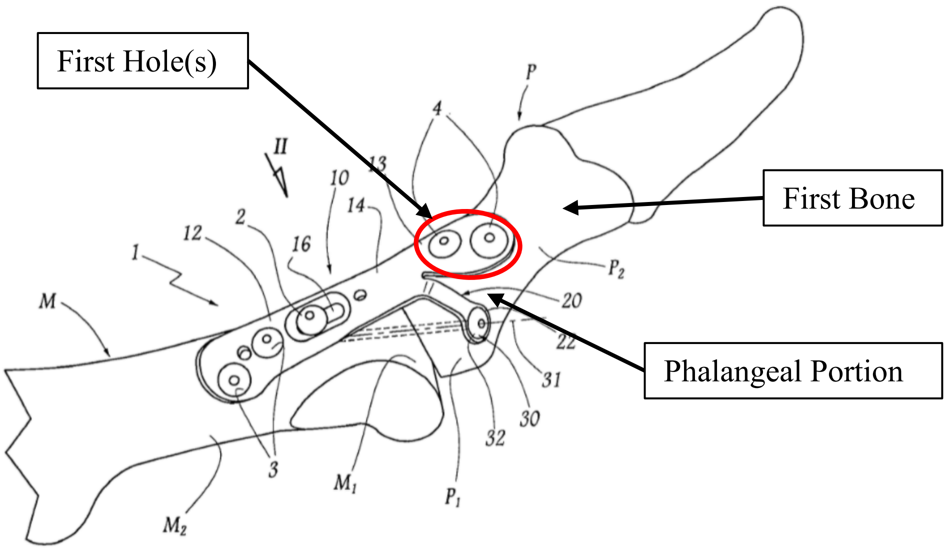


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶21, 34).

Arnould discloses this element. (Ex. 1002, ¶¶259-260).

iv. [1c]

Arnould's bone plate comprises holes 15_1 and 15_2 (second hole(s)) configured to attach to the metatarsal portion 12 (second end) of the plate 1 to the metatarsal (second bone):

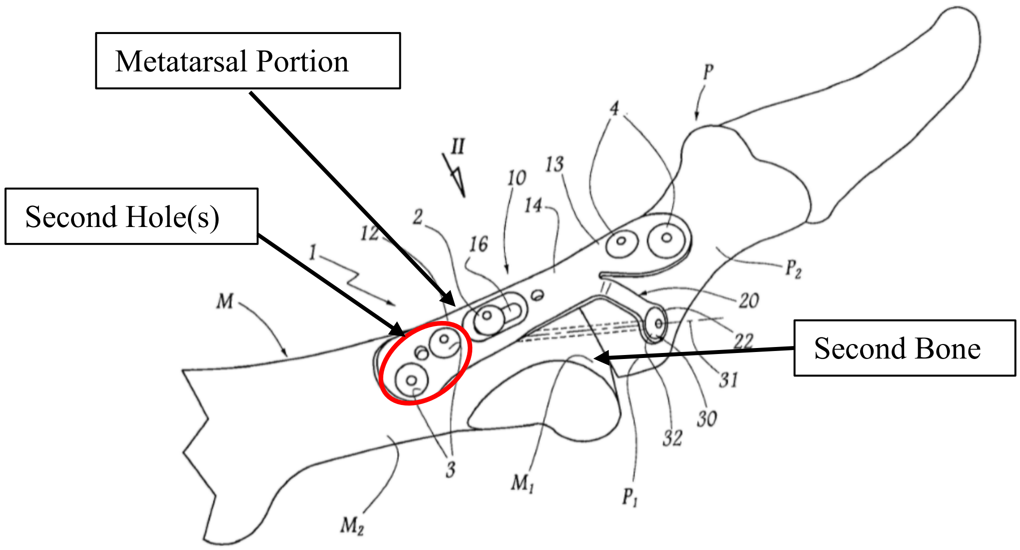


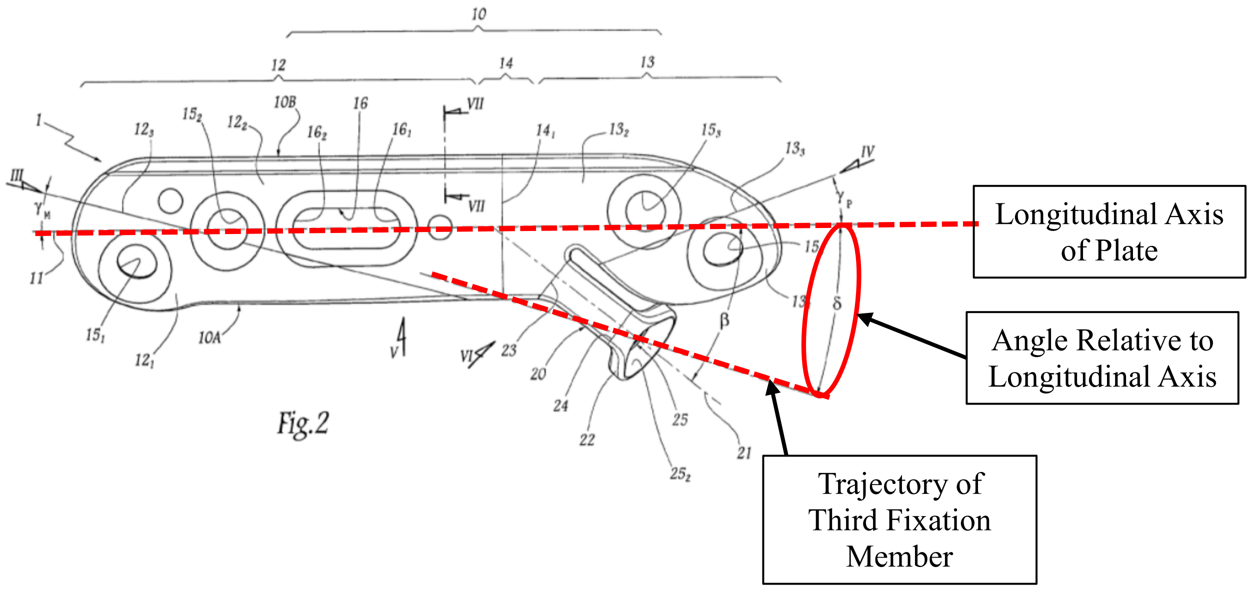
Fig. 1

(Ex. 1006, FIG. 1 (annotated); ¶¶21, 33).

Arnould discloses this element. (Ex. 1002, ¶¶261-262).

v. [1d]

Arnould discloses a screw 30 configured to be inserted into hole 25 at an angle δ selected by the surgeon:



(Ex. 1006, FIG. 2 (annotated); ¶32). The trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate (δ). (Ex. 1006, FIG. 2, ¶27; Ex. 1002, ¶263). Hole 25 is further connected to leg 20, where leg 20 is offset at angle β with respect to the longitudinal axis of the plate. (Ex. 1006, ¶25). A POSITA would understand that the hole 25 is a third hole that is offset at angle β relative to a longitudinal axis of the plate. (Ex. 1006, ¶25; Ex. 1002, ¶¶263-264).

A POSITA would also have looked to Zahiri for a way to provide better compression across the joint because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. (Ex. 1002, ¶265). Zahiri's bone plate comprises a barrel portion 38 with a third hole defined by an inner side wall 48 that extends from an opening 46 and a third point 3:

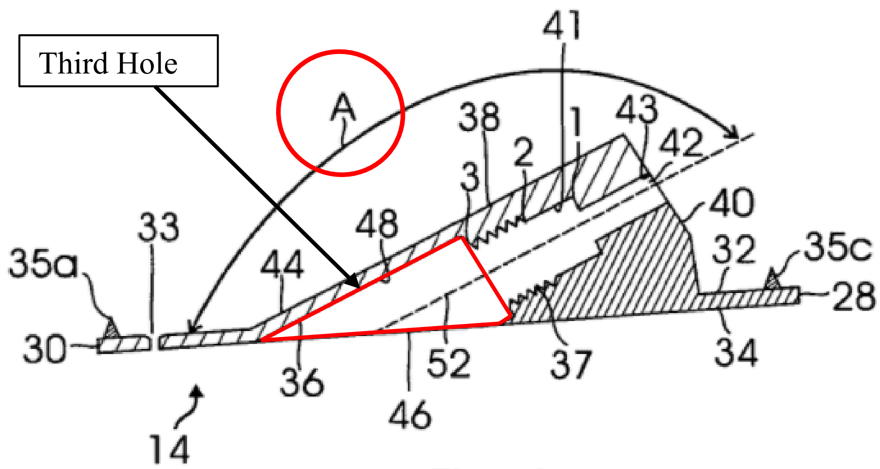


Fig. 4

(Ex. 1007, FIG. 4 (annotated); 6:12-35). The third hole is angle at an incline "A" relative to the central longitudinal line of the plate. (Ex. 1007, FIG. 4, 6:30-35, 6:50-56).

Zahiri further shows the barrel portion 238 (third hole) located between the first hole 233 and the second hole 235:

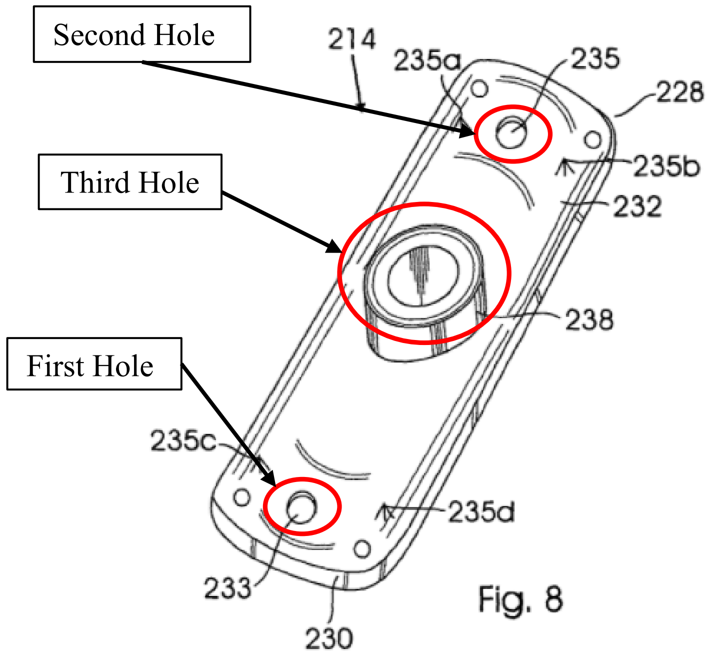


Fig. 8

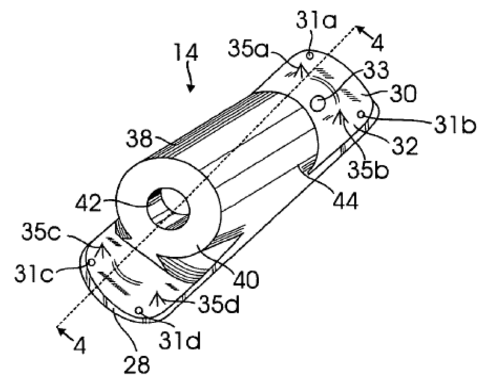


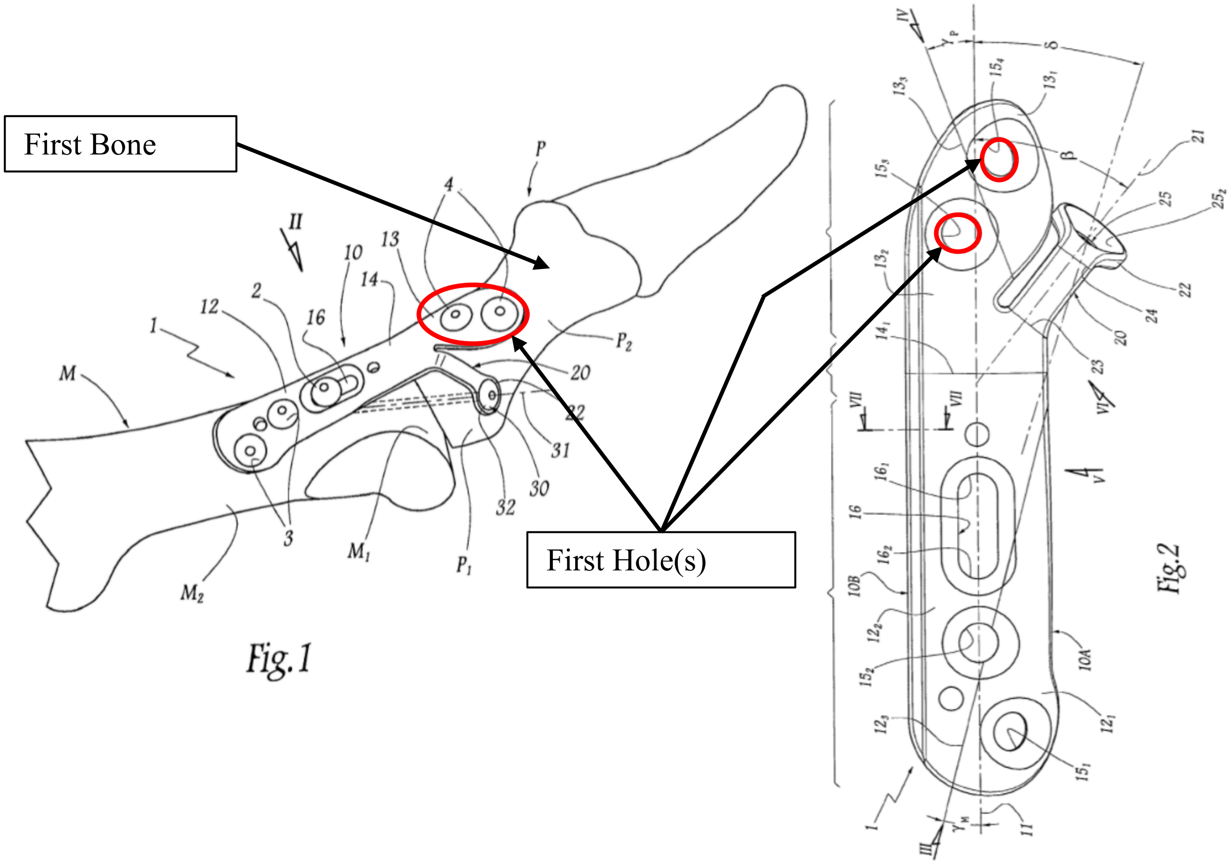
Fig. 3

(Ex. 1007, FIG. 3, 8 (annotated); 8:34-41). A POSITA would understand that the opening 238 is a third hole that is angled relative to a longitudinal axis of the plate and such a location would be easily implemented on the plate of Arnould to increase compressive forces. (Ex. 1002, ¶¶263-268).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶269).

vi. [1e]

Arnould discloses the steps of inserting screws 4 into holes 15_3 and 15_4, and attaching to the phalanx (first bone):

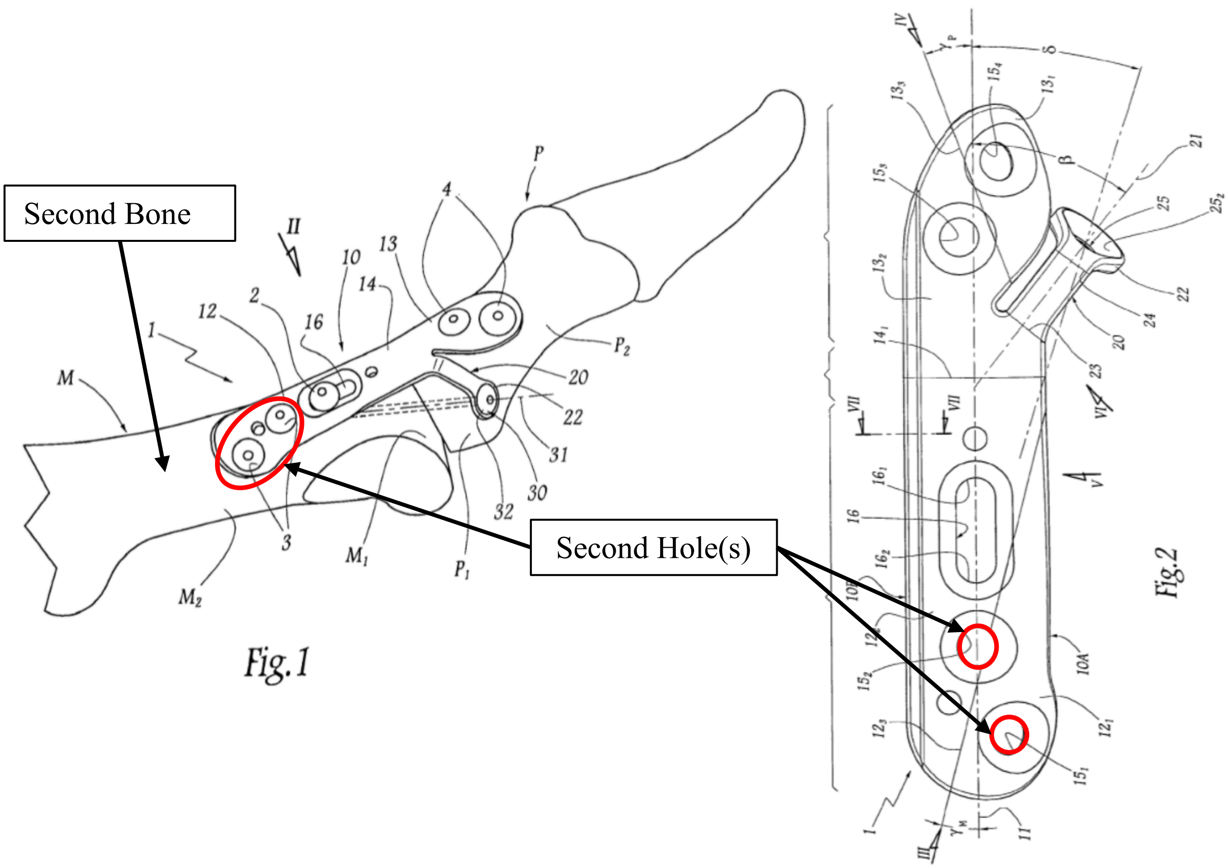


(Ex. 1006, FIGS. 1, 2 (annotated); ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶34 ("Before or after securing the plate body 10 in relation to the metatarsal M, additional screws 4 are inserted into the holes 15_3 and 15_4 in order to secure the phalangeal portion 13 to the phalanx P.")).

Arnould discloses this element. (Ex. 1002, ¶¶270-272).

vii. [1f]

Arnould discloses the steps of inserting screws 3 into holes 15_1 and 15_2, and attaching to the metatarsal (second bone):



(Ex. 1006, FIGS. 1, 2 (annotated); ¶21 ("In order to allow for the fixation of the plate body 10 to the metatarsal M and phalanx P, this body is provided with a series of through-holes, each adapted to receive a bone-anchoring screw or similar mechanical means in a complementary manner."); ¶33 ("The screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the

plate body 10 to the metatarsal M. This fixation is further strengthened by screwing screws 3 into the holes 15_1 and 15_2.”)).

Arnould discloses this element. (Ex. 1002, ¶¶273-275).

viii. [1g]

Arnould discloses a screw 30 configured to be inserted into hole 25 at an angle δ selected by the surgeon. (Ex. 1006, ¶32). Screw 30 is further configured to pass through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone). (Ex. 1006, ¶¶6, 32). A POSITA would understand that the free end of screw 30 resides in the second bone and does not attach to any portion of the bone plate. (Ex. 1002, ¶276).

A POSITA would find this element obvious in view of Arnould. (Ex. 1002, ¶277).

ix. [1h]

Arnould depicts a bone plate comprising one hole 25 configured to receive an angled screw 30 that passes through the phalangeal epiphysis (first bone) and anchor to the metatarsal epiphysis (second bone):

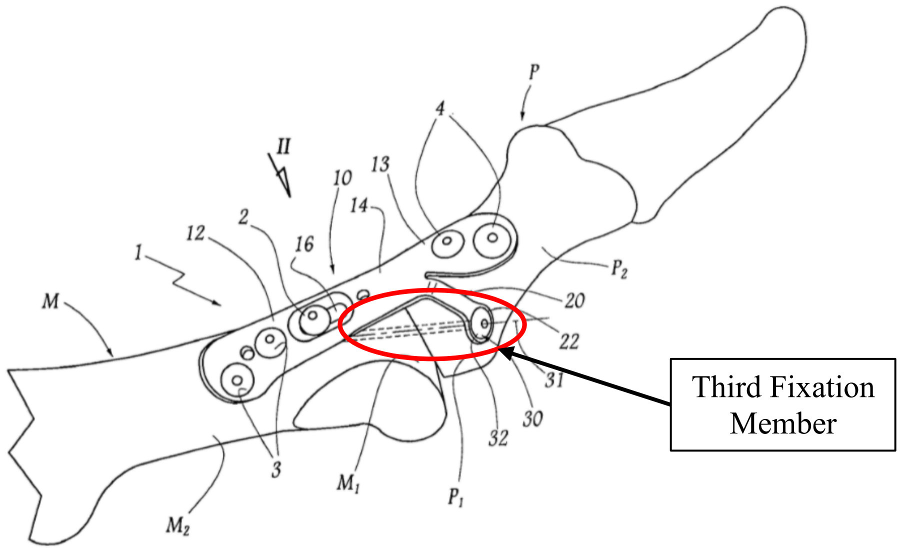


Fig. 1

(Ex. 1006, FIG. 1 (annotated); ¶32 ("The screw 30 is then inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at an angle δ, the value of which is chosen by the surgeon so that this screw, during its screwing, successively passes through the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, as explained above.")). Thus, Arnould discloses that the third fixation member is the only fixation member extending across said joint. (Ex. 1002, ¶¶278-279).

A POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw. (Ex. 1002, ¶280). Zahiri depicts a bone plate comprising a guide hole through a barrel portion configured to angle a lag screw through a first bone and into a second bone. (Ex. 1007, 2:23-36). Zahiri shows that

the bone plate is configured for only one lag screw 12 to pass through fracture line between the first bone and the second bone:

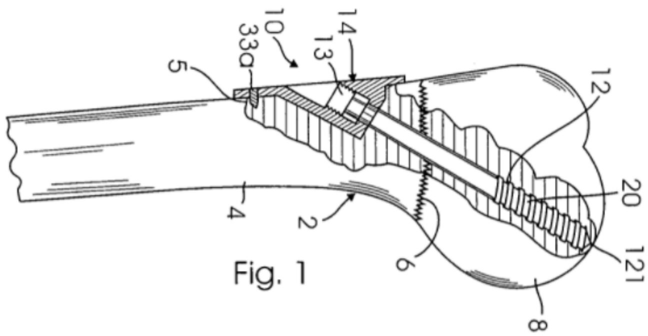


Fig. 1

(Ex. 1007, FIG. 1; 2:23-36). A POSITA would understand that the Arnould and Zahiri bone plates are configured for only one compression screw to intersect the joint and/or fracture line. (Ex. 1002, ¶280).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶281).

b. *Independent Claim 11*

i. [11Pre]

For at least the reasons in Section VII.F.2.a.i, Arnould discloses this element. (Ex. 1006, ¶11; Ex. 1002, ¶282).

ii. [11a]

For at least the reasons in Section VII.F.2.a.ii, Arnould discloses this element. (Ex. 1006, ¶14; Ex. 1002, ¶283).

iii. [11b]

For at least the reasons in Section VII.F.2.a.iii, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 34; Ex. 1002, ¶284).

iv. [11c]

For at least the reasons in Section VII.F.2.a.iv, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 33; Ex. 1002, ¶285).

v. [11d]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶286).

As discussed in Section VII.D.2.b.v, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 4, 8, 6:12-35, 8:34-44; Ex. 1002, ¶287). Looking for a way to improve the integrity of the angled fixation screw of Arnould's bone plate, a POSITA would consider the disclosure of Zahiri to implement this improvement. (Ex. 1002, ¶287).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶288).

vi. [11e]

The purpose of the fifth hole (as discussed below with respect to element 11k) is to receive a temporary fixation member. Arnould is silent regarding the use of

temporary fixation members with the guide holes shown in its figures. (Ex. 1002, ¶289). A POSITA would look to relevant prior art like Zahiri for disclosure of known temporary fixation members. (*Id.*).

As discussed in Section VII.D.2.b.vi, a POSITA would find Zahiri discloses this element. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18; Ex. 1002, ¶290). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device), and improve Arnould's plate to guide the plate alignment during implantation. (Ex. 1002, ¶290).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶291).

vii. [11f]

For at least the reasons in Section VII.F.2.a.vi, Arnould discloses this element. (Ex. 1006, FIGS. 1, 2, ¶¶21, 34; Ex. 1002, ¶292).

viii. [11g]

For at least the reasons in Section VII.F.2.a.vii, Arnould discloses this element. (Ex. 1006, FIGS. 1, 2, ¶¶21, 33; Ex. 1002, ¶293).

ix. [11h]

While Arnould discloses the use of a third fixation member that is angled into the first bone, across the joint, and into the second bone (Section VII.F.2.a.vii (citing

Ex. 1006, FIGS. 1, 2, ¶¶21, 33)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶294). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*).

As discussed in Section VII.D.2.b.ix, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 1, 4, 6:12-35, 2:23-28; Ex. 1002, ¶295). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to improve the integrity of the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶295).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶296).

x. [11i]

While Arnould discloses the use of a third fixation member that has a free end not attached to any portion of the bone plate and resides in the second discrete bone (Section VII.F.2.a.viii (citing Ex. 1006, ¶¶6, 32)), it lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole. (Ex. 1002, ¶297). A POSITA would look to prior art like Zahiri for disclosure of a fixation member used in such a configuration. (*Id.*).

As discussed in Section VII.D.2.b.x, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIG. 1, 2:23-28, 5:5-8; Ex. 1002, ¶298). A

POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the angled fixation screw of Arnould's plate with Zahiri's lag screw. (Ex. 1002, ¶298).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶299).

xi. [11j]

Arnould lacks sufficient disclosure of the full dimensions of the third fixation member. (Ex. 1002, ¶300). A POSITA would look to prior art like Zahiri for disclosure of a fixation member with a fixation head defining a head area, the head area being greater than the second area and less than the first area. (*Id.*).

As discussed in Section VII.D.2.b.xi, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIG. 1, 2:23-28; Ex. 1002, ¶301). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶301).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶302).

xii. [11k]

The purpose of the fifth hole is to receive a temporary fixation member. Arnould is silent regarding the use of temporary fixation members with the guide

holes shown in its figures. (Ex. 1002, ¶303). A POSITA would look to prior art like Zahiri for disclosure of known temporary fixation members. (*Id.*).

As discussed in Section VII.D.2.b.xii, a POSITA would find that Zahiri discloses this element. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶304). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve Arnould's plate to temporarily place the plate during implantation using Zahiri's pins. (Ex. 1002, ¶304).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶305).

c. *Independent Claim 17*

i. [17Pre]

For at least the reasons in Section VII.F.2.a.i, Arnould discloses this element. (Ex. 1006, ¶11; Ex. 1002, ¶306).

ii. [17a]

Arnould's plate comprise an outer longitudinal side 10B that faces outward and an inner longitudinal side 10B that presses against the surface of the bones. (Ex. 1006, ¶¶29, 23).

Arnould discloses this element. (Ex. 1002, ¶307).

iii. [17b]

For at least the reasons in Section VII.F.2.a.ii, Arnould discloses this element. (Ex. 1006, ¶14; Ex. 1002, ¶308).

iv. [17c]

For at least the reasons in Section VII.F.2.a.iii, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 34; Ex. 1002, ¶309).

v. [17d]

For at least the reasons in Section VII.F.2.a.iv, Arnould discloses this element. (Ex. 1006, FIG. 1, ¶¶21, 33; Ex. 1002, ¶310).

vi. [17e]

For at least the reasons in Section VII.F.2.a.v, Arnould discloses this element. (Ex. 1006, FIG. 2, ¶32; Ex. 1002, ¶311).

vii. [17f]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶312).

As discussed in Section VII.D.2.c.vii, a POSITA would find that Zahiri discloses this element. (Ex. 1007, 7:35-41; Ex. 1002, ¶313). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the

integrity of the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶313).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶314).

viii. [17g]

Arnould describes a screw hole 25 (third hole) configured such that the screw 30 (third bone screw) forms a non-zero angle in relation to the longitudinal direction of the plate body, and screw 30 passes through hole 25 and enters the phalanx and the metatarsal bone:

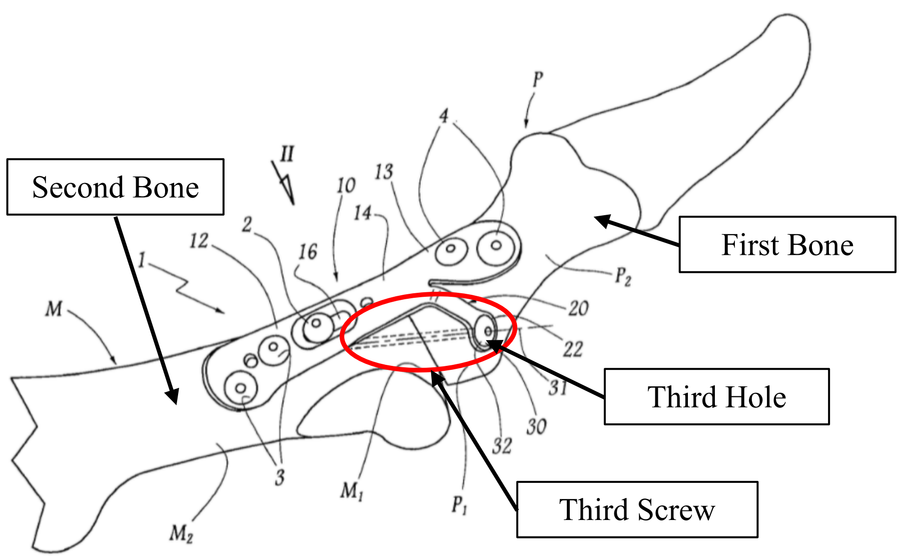


Fig.1

(Ex. 1006, FIG. 1 (annotated); ¶¶26-27). A POSITA would understand that screw 30 passes through the joint between the phalanx and the metatarsal. (Ex. 1002, ¶¶315-316).

A POSITA would find this element disclosed by Arnould. (Ex. 1002, ¶317).

ix. [17h]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶318).

As discussed in Section VII.D.2.c.ix, a POSITA would find that Zahiri discloses this element. (Ex. 1007, FIGS. 1, 4, 2:23-36, 7:31-38, 6:18-24; Ex. 1002, ¶319). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the integrity of the angled fixation screw of Arnould's plate by utilizing the seated head of the lag screw from Zahiri to ensure the third fixation member is seated securely in the third hole. (Ex. 1002, ¶319).

A POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1002, ¶320).

x. [17i]

For at least the reasons in Section VII.F.2.b.vi, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18; Ex. 1002, ¶321).

xi. [17j]

For at least the reasons in Section VII.F.2.b.xii, a POSITA would find this element obvious in view of Arnould and Zahiri. (Ex. 1007, 3:11-18, 7:19-24, 7:63-7:66; Ex. 1002, ¶322).

d. *Dependent Claims 2-3, 7-10, 12-16, and 18*

i. Claim 2

Arnould discloses a bone plate comprising predetermined contours necessary to secure to the metatarsal and phalangeal, and to conform to the upper surface of the diaphyseal portion of the metatarsal, which are both bones in the human foot. (Ex. 1006, ¶¶1, 15, 39; Ex. 1002, ¶323).

Arnould discloses this element. (Ex. 1002, ¶324).

ii. Claim 3: The system of claim 1 wherein said joint…

Arnould's arthrodesis bone plate is configured "for the joint between the first metatarsal and the first phalanx of the big toe," and to be "placed and fixed on the metarsal-phalangeal joint locked by the plate." (Ex. 1006, FIG. 1, ¶¶1, 10).

Arnould discloses this element. (Ex. 1002, ¶¶325-326).

iii. Claim 7

Arnould discloses a fixation screw 30 that is configured to be tightened such that the metatarsal and the phalanx are substantially contiguous. (Ex. 1006, ¶32). Zahiri's bone plate comprises a lag screw configured to compress the diaphyseal

(Ex. 1006, FIG. 1 (annotated); ¶¶32-33). A POSITA would understand that the free end of screw 30 and screws 3 would reside adjacent to each other in the metatarsal. (Ex. 1002, ¶¶329-330).

A POSITA would find this element obvious in view of Arnould. (Ex. 1002, ¶331).

v. Claim 9

For at least the reasons in Sections VII.F.2.b.vi and VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:63-7:66; Ex. 1002, ¶332).

vi. Claim 10

For at least the reasons in Sections VII.F.2.b.vi and VII.F.2.b.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1007, FIGS. 2, 8, 5:47-64, 3:11-18, 7:63-7:66; Ex. 1002, ¶333).

vii. Claim 12

For at least the reasons in Section VII.F.2.d.i, a POSITA would find that this claim is taught by Arnould. (Ex. 1006, ¶15, 39; Ex. 1002, ¶334).

viii. Claim 13

For at least the reasons in Section VII.F.2.d.iv, a POSITA would find this claim obvious in view of Arnould and Zahiri. (Ex. 1006, ¶32; Ex. 1002, ¶335).

G. Ground 5: Claim 6 is Unpatentable Under 35 U.S.C. §103(a) as Obvious over Arnould, Zahiri, and Myerson

Dependent claim 6 is obvious in view of Arnould, Zahiri, and Myerson. (Ex. 1002, ¶341).

1. Basis for Combination of Arnould, Zahiri, and Myerson

A POSITA would be motivated to combine Arnould and Zahiri for at least the reasons in Section VII.E.1.

Myerson teaches that "the plate 10 is configured to be positioned anywhere in the mid-foot." (Ex. 1010, ¶21). Myerson guides a POSITA to substitute differently contoured plates in order for the plate to be positioned across the cuboid bone. (Ex. 1010, ¶¶21-22; Ex. 1002, ¶¶342-343). A POSITA would understand, that if a joint in the mid-foot needed to be fused, Arnould's bone plate would be modified to conform to the bones in the mid-foot. (Ex. 1002, ¶¶344).

2. Claim 6

Arnould discloses a bone plate is configured to conform to the anatomical contours of the domed metatarsal zone. (Ex. 1006, ¶15). In analogous art, Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones "anywhere along the mid-foot," "especially across the metatarsal joints." (Ex. 1010, ¶¶21-22). Myerson illustrates a bone plate fixed across the tarsometatarsal joint:

IX. CLAIM APPENDIX OF THE CHALLENGED CLAIMS

[1pre] A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:

[1a] a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:

[1b] a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint;

[1c] a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and

[1d] a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate;

[1e] a first fixation member configured to be inserted through the first hole of the bone plate and into the first discrete bone of the joint;

[1f] a second fixation member configured to inserted through said second hole of said bone plate and into the second discrete bone of said joint; and

[1g] a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in the second discrete bone,

[1h] wherein said third fixation member is the only fixation member extending across said joint from the first side of the joint to the second side of the joint.

[11pre] A system for fusing first and second bone parts, said system comprising:

[11a] a bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint, said bone plate having;

[11b] a first hole configured to align with the first bone part,

[11c] a second hole configured to align with the second bone part,

[11d] a third hole and a fourth located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area, and

[11e] a fifth hole located adjacent either the first hole or the second hole, said fifth hole being smaller in area than said first hole or said second hole;

[11f] a first fixation member configured to be inserted through the first hole of said bone plate and into the first bone part;

[11g] a second fixation member configured to be inserted through the second hole of said bone plate and into the second bone part;

[11h] a third fixation member configured to be inserted through the third and fourth hole in the bone plate, into the first bone part, across the fracture or joint, and into the second bone part, wherein a free end of said third fixation member does not attach to any portion of the bone plate and wherein the third fixation member is the only fixation member extending across the fracture or joint, the third fixation member having a fixation head defining a head area, the head area being greater than the second area and less than the first area; and

[11i] a temporary fixation member configured to be inserted through the fifth hole in the bone plate.

[12] The system of claim 11 wherein the bone plate is contoured to anatomically fit bones in a human foot.

[13] The system of claim 11 wherein the free end of the third fixation member and a free end of the second fixation member are configured to reside adjacent each other within said second bone part.

[14] The system of claim 11 wherein the bone plate is substantially planar.

[15] The system of claim 11 wherein the fifth hole is a pin hole.

[16] The system of claim 11 wherein the temporary fixation member is a guide pin.

[17Pre] An orthopedic implant comprising;

[17a] a bone plate having a proximal surface and an opposite distal bone contacting surface, said bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint,

[17b] said bone plate having a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw,

[17c] a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw,

[17d] a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate, and

[17e] a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner,

v.

Stryker European Operations Holdings LLC
Patent Owner.

Case No. 2022-00488
Patent No. 10,993,751

PATENT OWNER'S PRELIMINARY RESPONSE

reasons, Petitioner has failed to demonstrate a reasonable likelihood of prevailing on Ground 2 at least as to claim 11.

4. Petitioner Fails To Demonstrate That The Slater-Zahiri Combination Satisfies All Elements Of Claim 17

Petitioner's analysis of claim 17 of Ground 2 showcases its excessive use of abbreviations and short-cuts, falling far short of meeting the requirements of 35 U.S.C. § 312(a)(3). *See id.* ("A petition must "identif[y], in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim . . . .").

First, rather than quoting the claim language in the headings of the Petition or in the body of the Petition, Petitioner uses abbreviated headings that make it difficult to determine which claim element Petitioner is intending to reference. While Petitioner includes a Claim Appendix of the Challenged Claims where Petitioner has broken out the independent claims into separate claim elements and assigned each element an abbreviation, the claim element abbreviations used in the headings of the Petition do not necessarily match up with the claim element abbreviations used in the Claim Appendix. As shown below, in some instances, the claim element

abbreviations used in some of the headings do not even appear in the Claim Appendix at all.[6]

From the Petition	From the Appendix
iv. [17c] said bone plate having a first hole… *See* Petition at p. 48; *see also id.* at p. 83	[17c] a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw, *See* Petition at p. 97
v. [17d] a second hole… *See* Petition at p. 48; *see also id.* at p. 83	[17d] a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate, and *See* Petition at p. 97
vi. [17e] a third hole… *See* Petition at p. 48; *see also id.* at p. 83	[17e] a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member. *See* Petition at p. 97
vii. [17f] said third hole sized… *See* Petition at p. 48; *see also id.* at p. 83	There is no [17f] found in the Appendix *See* Petition at p. 97
viii. [17g] said third hole being angled… *See* Petition at p. 49; *see also id.* at p. 84	There is no [17g] found in the Appendix *See* Petition at p. 97
ix. [17h] said third hole being configured… *See* Petition at p. 50; *see also id.* at p. 85	There is no [17h] found in the Appendix *See* Petition at p. 97
x. [17i] a pin hole located… *See* Petition at p. 54; *see also id.* at p. 85	There is no [17i] found in the Appendix *See* Petition at p. 97
xi. [17j] said pin hole extending… *See* Petition at p. 54; *see also id.* at p. 86	There is no [17j] found in the Appendix *See* Petition at p. 97

[6] For the sake of brevity, Patent Owner is using claim 17, Ground 2 as an example. This is, by no means, an isolated example. The Petition repeatedly includes abbreviated references in the headings that do not match up with the Claim Appendix. *See, e.g.*, Petition at 42-45 ([11i] – [11k]); Petition at 81-82 ([11j] – [11k]); Petition at 83-86 ([17f] – [17j]).

Nor does Petitioner recite the claim limitations within the argument section, instead favoring the shorthand "Slater discloses this element" or "the combination teaches this element." *See, e.g.*, Petition at 47-54. "There is no way to understand many of Petitioner's arguments without an understanding of the meaning of these abbreviations." *Lenovo (U.S.) Inc. v. Litl LLC*, IPR2021-00681, Paper 8 at 15 (P.T.A.B. Sept. 3, 2021) (finding extensive use of abbreviations to "exacerbate[] the [petition's] lack of clarity"). With no corresponding language in the claim appendix, the "Petition's analysis is largely divorced from the claim language and its specific requirements," therefore lacking the requisite particularity under 35 U.S.C. § 312(a)(3). *DirecTV, LLC v. Qurio Holdings, Inc.*, IPR2015-02007, Paper 6 at 8 (P.T.A.B. Apr. 4, 2016).

Second, in lieu of setting forth particularized arguments, Petitioner repeatedly provides internal cross references that are incorrect or nonsensical. For example, under heading "[17Pre] An orthopedic implant comprising," Petitioner argues only that "[f]or at least the reasons in Section VII.C.2.a.i., Slater discloses this element." *See* Petition at 47. But Section VII.C.2.a.i. references "[1Pre] A system for fusing…" with no mention of any "orthopedic implant." *Id.* at 13. Regardless of whether, in this particular instance, it would be apparent to a POSITA that a reference is directed to an orthopedic implant, it is Petitioner's burden to establish that the prior art references teach or render obvious the claimed invention. It is not up to Patent

Owner to decipher Petitioner's positions. *See Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2015-01402, Paper 18 at 13 (P.T.A.B. Oct. 21, 2015) ("it is not Patent Owner's responsibility in the first instance to identify differences."); *see also Gracenote, Inc. v. Iceberg Indus. LLC*, IPR2013-00552, Paper 6 at 21, 22 (P.T.A.B. Mar. 7, 2014) ("To the extent such unexplained citations qualify as argument, they are inadequate to demonstrate that elements of the challenged claims are inherent in the cited references . . . .").

Moreover, under heading "[17b] said bone plate having…," which the Claim Appendix identifies as "said bone plate having a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw," Petitioner argues only that "[f]or at least the reasons in Section VII.C.2.a.ii, a POSITA would find that Slater discloses this element." *Id.* at 47, 97. But Section VII.C.2.a.ii. references "[1a] a bone plate having…," which the Claim Appendix identifies as "a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:" *Id.* at 14, 93. Claim element [1a] does not recite a "first hole" much less "a first hole configured to align with the first bone part, the first hole sized to accept a first bone screw" as recited in claim element [17b]. In other words, the cited cross-

reference clearly does not support element [17b], but is the only argument provided.[7] Petitioner's approach obscures its substantive positions and improperly forces Patent Owner and the Board to "play archeologist with the record." *Apple v. Contentguard Holdings, Inc.*, IPR2015-00442, Paper 9 at 9-10 (P.T.A.B. Jul. 13, 2015) (citing *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 10 (P.T.A.B. Aug. 29, 2014)).

Third, Petitioner repeatedly provides internal cross references between the various grounds ***without reconciling the differences in claim limitations***. With respect to the preamble of claim 17 (reciting "[a]n orthopedic implant"), Petitioner indicates that "[c]ertain elements of claim 17 are identical to elements of claim 1 except that claim 1 is directed to a system for fusing two discrete bones whereas claim 17 is directed to an implant positionable alongside first and second bone parts straddling the fracture or joint." *See* Petition at 47, fn. 5. However, in many instances, Petitioner provides internal cross references even though the claim language differs in ***additional*** ways.

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[7] Without belaboring the point, these types of errors and inconsistencies pervade the entire Petition. *See, e.g.*, Petition at 35 ("[11a] a bone plate having" referring to Section VII.C.2.a.ii ("[1a] a bone plating having") at 14).

For example, the Petition provides a heading for "[17i] a pin hole located. . ." (which is not found in the Claim Appendix) and argues only that "[f]or at least the reasons in Section VII.D.2.b.vi, a POSITA would be motivated to combine Slater and Zahiri, and would find the combination teaches this element." *See* Petition at 54. Yet, Section VII.D.2.b.vi relates to "[11e] a fifth hole . . . ." *See* Petition at 38-39. Petitioner wholly fails to provide any analysis reconciling "a pin hole" with "a fifth hole" and merely relies on conclusory statements and citations to the Sherman Declaration that provide the same deficient cross-reference. *See* Ex. 1002 at ¶214. In fact, Petitioner repeatedly makes the same nonsensical cross references to various claim limitations without explaining, let alone acknowledging, the differences in the claim language. *See, e.g.*, Petition at 56 ("Claim 9" referring to Section VII.D.2.b.vi ("[11e]") at 38 and Section VII.D.2.b.xii ("[11k]") at 45-46), *id.* at 56 ("Claim 10" referring to Section VII.D.2.b.vi ("[11e]") at 38 and Section VII.D.2.b.xii ("[11k]") at 45-46).[8]

[8] This is not an exhaustive list. Petitioner makes the same mistakes with respect to at least Ground 4. *See, e.g.*, Petition at 85 ("[17i]" referring to Section VII.F.2.b.vi ("[11e]") at 78), 86 ("[17j]" referring to Section VII.F.2.b.xii ("[11k]") at 81), 88 ("Claim 9" referring to Section VII.F.2.b.vi ("[11e]") at 78 and Section VII.F.2.b.xii

Petitioner's analysis of claim element "[17a] a bone plate…", which the Claim Appendix identifies as "a bone plate having a proximal surface and an opposite distal bone contacting surface, said bone plate having a length sufficient to span a fracture or joint of a patient such that said bone plate is positionable alongside first and second bone parts straddling the fracture or joint," is even more confusing. *See* Petition at 47, 97. Petitioner argues only that "Slater's bone plate comprises 'an outer surface 21 and an inner surface 22 with is opposes [*sic*] anterior surface 23 of tibia 4." *Id.* at 47. Of course, "a petition should include a detailed explanation of the significance of the quotations and citations from the applied references." *Avant Tech., Inc. v. Anza Tech., Inc.*, IPR2018-00828, Paper 7 at 12 (P.T.A.B. Oct. 16, 2018). To the extent Petitioner's argument can be understood, it would appear to address, at most, the first portion of claim element [17a] ("a bone plate having a proximal surface and an opposite distal bone contacting surface.").

Even if Petitioner intended to address the latter portion of claim element [17a] under its mislabeled heading "[17b] said bone plate having…," its reference to Section VII.C.2.a.ii makes no sense because claim 17 does not recite "said bone plate having a first end and a second end along said length, said length ***defining a***

("[11k]") at 81), 88 ("Claim 10" referring to Section VII.F.2.b.vi ("[11e]") at 78 and Section VII.F.2.b.xii ("[11k]") at 81).

longitudinal axis" while claim 1 does. Again, Petitioner simply ignores any differences in claim language and, due to the overall sloppiness of the Petition, it is unclear whether Petitioner contends that the claim language should be construed identically, or whether Petitioner simply did not notice the difference in the claim language. In either case, it is not up to Patent Owner or the Board to have to decipher Petitioner's arguments.

The Board should deny institution of the Petition for failing to comply with 35 U.S.C. § 312(a)(3). *See Lenovo (U.S.) Inc. v. Ltl LLC*, IPR2021-00681, Paper 8 at 14 (P.T.A.B. Sept. 3, 2021) (denying institution); *DirecTV, LLC v. Qurio Holdings, Inc.*, IPR2015-02007, Paper 6 at 15 (P.T.A.B. Apr. 4, 2016) (same).

5. Petitioner's "Basis for Combination" Does Not Remedy The Deficiencies of Petitioner's Ground 2 Obviousness Arguments

At the outset of its Ground 2 analysis, Petitioner includes a separate omnibus section under the heading "Basis for Combination," which purports to include the bases for combining Slater and Zahiri to render obvious claims 1-2 and 7-18. However, this section primarily discusses fixation screws configured to intersect a joint through two discrete bones, and Petitioner's argument that "there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture." At most, Petitioner's "joint versus fracture" argument may help to show that a POSITA may have been capable of combining Slater and Zahiri, not that a

2. Petitioner Fails To Demonstrate That Claim 11 Is Obvious Over Arnould And Zahiri

Petitioner's analysis of independent claim 11 in view of Arnould and Zahiri is similarly deficient. The Claim Appendix indicates that [11d] refers to the limitation "a third hole and a fourth [hole] located between the first hole and the second hole, said third and fourth hole having an axis that is configured to cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area."

Despite the number of distinct limitations described in claim element [11d], the entirety of Petitioner's analysis fits on half of a page. Petition at 78. Here, under the heading "[11d]," Petitioner simply states "Arnould is silent regarding the dimensions of hole 25. *Id.* A POSITA would look to prior art like Zahiri for disclosures of the known dimensions of such openings." *Id.* It is entirely unclear what this means and how it relates to claim element [11d]. It is unclear whether Petitioner intends for "hole 25" to refer to the "third hole" or the "fourth hole." And it is unclear what Petitioner means when it references Zahiri as providing "known dimensions of such openings." As usual, the Sherman Declaration provides no clarity as it simply repeats the same confusing language. *See* Ex. 1002 at ¶286.

To further confuse matters, Petitioner provides a cross reference to "Section VII.D.2.b.v," its earlier analysis of "[11d] a third hole. . ." for Ground 2 (obviousness based on Slater and Zahiri), to support its argument that "a POSITA would find that

Zahiri discloses this element." Petition at 78. The problems relating to Petitioner's mixing and matching of Zahiri embodiments, together with its failure to acknowledge that it relied on two distinct embodiments within Zahiri, are described *supra* with respect to Ground 2. Moreover, to the extent that Petitioner relies on any alleged motivation to combine ***Slater*** with Zahiri to somehow support a motivation to combine ***Arnould*** with Zahiri, such reliance is improper because Petitioner fails to explain why any such arguments would be cross-applicable.[9] *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1379 (Fed. Cir. 2016) ("McClinton merely attempted to incorporate its arguments based on Alpha to its obviousness analysis based on Lehr, without presenting particularized arguments explaining why those arguments from Alpha would be cross-applicable to the Lehr reference.").

Of course, Petitioner also cannot properly establish obviousness by simply concluding that "[l]ooking for a way to improve the integrity of the angled fixation screw of Arnould's bone plate, a POSITA would consider the disclosure of Zahiri to

[9] Petitioner's cross reference to the alleged combination of Slater and Zahiri is a general theme throughout Ground 4, as is the failure to explain any perceived cross-applicability. *See, e.g.*, Petition at 80 (citing to "Section VII.D.2.b.ix" of Slater and Zahiri), 80 (citing to "Section VII.D.2.b.x" of Slater and Zahiri), 82 (citing to "Section VII.D.2.b.xii" of Slater and Zahiri).

cross the fracture or joint during use, the third hole defining a first area and the fourth hole defining a second area, the second area being smaller than the first area."

3. Petitioner Fails To Demonstrate That Claim 17 Is Obvious Over Arnould And Zahiri

As in Ground 2, Petitioner's abbreviated headings, insufficient evidence, deficient combinations, and improper cross references to different claims and different grounds are similarly present in its allegations for Ground 4, claim 17. For example, as discussed above in Ground 2, Petitioner fails to establish that Arnould or Zahiri disclose "a third hole located between said first hole and said second hole." Additionally, in what appears to be arguments directed to "said third hole sized to accept a third bone screw," Petitioner provides a cross reference to "Section VII.D.2.c.vii." for the alleged combination of ***Slater*** and Zahiri without explaining how the combination applies to ***Arnould*** and Zahiri. Petition at 83; *See In re Magnum Oil Tools Int'l*, 829 F.3d at 1379. An explanation regarding a reasonable expectation of success for combining Arnould and Zahiri is also missing.

4. Petitioner's "Basis for Combination" Does Not Remedy the Deficiencies of Petitioner's Ground 4 Obviousness Arguments

Petitioner once again includes a separate catch-all section under the heading "Basis for Combination," which purports to include the bases for combining Arnould and Zahiri to render obvious claims 1-3 and 7-18. As discussed above with respect to Ground 2, Zahiri is directed to a fixation device for a large, long bone, *i.e.,* a

Trials@uspto.gov
571-272-7822

Paper 8
Entered: August 12, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC,
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

IPR2022-00488
Patent 10,993,751 B1

Before HYUN J. JUNG, SUSAN L. C. MITCHELL, and
MICHAEL A. VALEK, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

temporary guide pins to hold the bone plate in place while the lag screw of Zahiri is inserted ensuring proper alignment during implantation and prevention of discomfort and abnormalities. *Id.* ¶ 137 (citing Ex. 1007, 3:10–18).

We credit Mr. Sherman's testimony on this record and his conclusion that Zahiri discloses a known technique for improving plate alignment during implantation that when combined with Slater's bone plate "would support Slater's goal of reducing the risk of complications and improving the likelihood of painless, normal walking by the patient." Ex. 1002 ¶ 138; *see* Pet. 33.

Finally, Patent Owner takes issue with Petitioner's discussion of how the limitations of claim 17 are taught or suggested by the combination of Slater and Zahiri. Prelim. Resp. 34–40. Patent Owner asserts that the claim element abbreviations in Petitioner's analysis do not match the abbreviations in the Petitioner's claims appendix and inappropriately internally cross reference to previous portions of the Petition analyzing different claim elements that do not necessarily coincide in scope with the limitations at issue in claim 17. *Id.* at 34–41. We need not resolve this issue here to determine whether to institute and invite the parties to address this issue in further briefings.

Accordingly, based on the current record, Petitioner has established a reasonable likelihood it will prevail in demonstrating that at least independent claims 1 and 11 would have been obvious over Slater and Zahiri.

anchor to the metatarsal epiphysis). Pet. 67–77 (citing evidence). Petitioner relies on Zahiri as additional evidence for elements [1d] and [1h] and, based on the current record, has articulated a sufficient rationale for combining Zahiri's teachings regarding those limitations with Arnould to the extent they are not already taught in Arnould itself. Pet. 62–66, 70–72, 76–77 (citing evidence).

Patent Owner asserts that Petitioner fails to show that Arnould teaches "a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate" from element [1d]. Prelim. Resp. 44–45. From Petitioner's annotated Figure 2 and discussion concerning screw 30 and hole 25, it appears that hole 25 is between the first and second holes as required. *See* Pet. 70. It also appears that Petitioner has explained sufficiently using annotated Figure 2 and paragraph 27 of Arnould that "[t]he trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate (δ)." Pet. 70 (citing Ex. 1006, Fig. 2, ¶ 27; Ex. 1002 ¶ 263). Mr. Sherman testifies that "[b]ased on Figure 2, Arnould clearly discloses a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate." Ex. 1002 ¶ 264. We credit Mr. Sherman's testimony on the record before us. Petitioner's statement of equivocation that "it may be argued" that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate does not undermine this testimony. Prelim. Resp. 35–36. We need not reach Patent Owner's assertions concerning the teachings of Zahiri here because we determine that the

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner,

v.

Stryker European Operations Holdings LLC,
Patent Owner.

Case No. IPR2022-00488

Patent No. 10,993,751

PATENT OWNER'S RESPONSE

Petitioner explain why a POSITA would have been motivated to combine this aspect of Zahiri with Slater. As discussed above, a POSITA would ***not*** have combined Zahiri's unique locking screw-lag screw combination with Slater as such a combination would destroy the advantages of the Slater bone plate. (EX2005, ¶¶173-174).

iii. Claim Elements [11e] and [11i]

Petitioner relies solely on Zahiri for claim elements [11e] and [11i] (mislabeled in the Petition as [11k]) because "Slater is silent regarding the use of temporary fixation members.") (Pet., 38, 45-46, 95-96). Petitioner claims that "[a] POSITA would look to improve the disclosure of Slater through the use of temporary alignment techniques as taught by Zahiri." (*Id*., 39, 46). For the reasons described in Sections V.B.1.c-e., Petitioner is wrong. (EX2005, ¶¶175-177).

c. Claim 17

Petitioner's analysis of independent claim 17 is incomprehensible, falling far short of meeting the requirements of 35 U.S.C. § 312(a)(3). *See id.* ("A petition must "identif[y], in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim . . . ."). For example, while Petitioner includes a Claim Appendix of the Challenged Claims purporting to break

the independent claims into separate claim elements, the claim element abbreviations used in the Petition's headings largely do not match up with the claim element abbreviations used in the Claim Appendix.

From the Petition	From the Appendix
iv. [17c] said bone plate having a first hole… *See* Petition at p. 48; *see also id.* at p. 83	[17c] a second hole configured to align with the second bone part, the second hole sized to accept a second bone screw, *See* Petition at p. 97
v. [17d] a second hole… *See* Petition at p. 48; *see also id.* at p. 83	[17d] a third hole located between said first hole and said second hole, said third hole sized to accept a third bone screw having a screw head, said third hole being angled relative to said bone plate such that, during use, said third bone screw is positioned to extend through said third hole and cross the fracture or joint, said third hole being configured to allow the entire screw head to be seated below the proximal surface of said bone plate, and *See* Petition at p. 97
vi. [17e] a third hole… *See* Petition at p. 48; *see also id.* at p. 83	[17e] a pin hole located adjacent either said first hole or said second hole, said pin hole being smaller in area than said first hole or said second hole, said pin hole extending from said proximal surface of said bone plate to said distal surface, said pin hole being configured to accept a temporary fixation member. *See* Petition at p. 97
vii. [17f] said third hole sized… *See* Petition at p. 48; *see also id.* at p. 83	There is no [17f] found in the Appendix *See* Petition at p. 97
viii. [17g] said third hole being angled… *See* Petition at p. 49; *see also id.* at p. 84	There is no [17g] found in the Appendix *See* Petition at p. 97
ix. [17h] said third hole being configured… *See* Petition at p. 50; *see also id.* at p. 85	There is no [17h] found in the Appendix *See* Petition at p. 97
x. [17i] a pin hole located… *See* Petition at p. 54; *see also id.* at p. 85	There is no [17i] found in the Appendix *See* Petition at p. 97
xi. [17j] said pin hole extending… *See* Petition at p. 54; *see also id.* at p. 86	There is no [17j] found in the Appendix *See* Petition at p. 97

Nor does Petitioner recite the claim limitations within the body of the argument, instead favoring the shorthand "Slater discloses this element" or "the combination teaches this element. (Pet., 47-54). Worse, instead of setting forth

particularized arguments, Petitioner repeatedly provides internal cross-references that are incorrect or nonsensical, without reconciling the differences in claim limitations. (Pet., 35 ("[11a]" referring to Section VII.C.2.a.ii ("[1a]") at 14; Pet., 54 ("[17i]" referring to Section VII.D.2.b.vi ("[11e]") at 38-39; *Id.*, 85 ("[17i]" referring to Section VII.F.2.b.vi ("[11e]") at 78); *Id.*, 86 ("[17j]" referring to Section VII.F.2.b.xii ("[11k]") at 81); *Id.*, 88 ("Claim 9" referring to Section VII.F.2.b.vi ("[11e]") at 78 and Section VII.F.2.b.xii("[11k]") at 81); *Id.*, 88 ("Claim 10" referring to Section VII.F.2.b.vi ("[11e]") at 78 and Section VII.F.2.b.xii ("[11k]") at 81). The Board should find that the Petition fails to comply with 35 U.S.C. § 312 (a)(3). *See Lenovo (U.S.) Inc. v. Ltl LLC*, IPR2021-00681, Paper 8 at 14 (P.T.A.B. Sept. 3, 2021) ("This approach of forcing the reader to follow a web of nested cross-references to find Petitioner's arguments improperly shifts the burden of deciphering Petitioner's arguments onto Patent Owner and the Board.")); *DirecTV, LLC v. Qurio Holdings, Inc.*, IPR2015-02007, Paper 6 at 15 (P.T.A.B. Apr. 4, 2016) (same).

i. Claim Element [17d]

In addressing mislabeled claim element "[17h]," which appears to include the last clause of "[17d]" set forth in the Claim Appendix, Petitioner alleges that Slater "Figures 1 and 2 show depth to opening 26 in formation 27 to allow for the screw head to be countersunk, or seated below the plate." (Pet., 51, 97). In an annotated

internal fixation device "for use in a transverse fracture of a humerus" would be modified for a plate that is placed "on the upper surfaces of the metatarsal and phalanx connected by the joint." (EX1007, Title; EX1006, ¶8; EX2005, ¶249).

For the above reasons, Arnould teaches away from Zahiri. Combining Zahiri with Arnould would take away important advantages of Arnould, namely, a design specifically contoured for a metatarsophalangeal joint, and a surgeon's ability to contour and adapt the Arnould plate according to a desired dorsiflexion angle. (*Id.*, ¶250).

c. Petitioner's Combination is Based on Improper Hindsight

Petitioner's incorporation of Zahiri's "temporary guide pins used with pin holes" into the Arnould plate is solely based on impermissible hindsight. (Pet., 66). Petitioner concedes that "Arnould lacks sufficient disclosure regarding temporary fixation members in the guide holes." (*Id.*, 65). As discussed *supra*, however, the "pin holes" and "four tips" of Zahiri were a specific improvement to the '055 patent and were added to solve the problem of torqueing, or spinning of the guide plate on the humeral cortex as the lag screw was advanced into the epiphysis. (EX1007, 1:55-61, 3:41-44, 5:52-59, Fig. 3; Section V.B.1.c-e). With the '055 patent device having no fixation members other than the lag screw, Zahiri provided additional

fixation to stabilize the device during insertion of the lag screw. (EX2005, ¶¶251-252).

Arnould's disclosure renders unnecessary Zahiri's "known technique for improving plate alignment during implantation." (Pet., 66). A POSITA would understand that the pre-existing screw holes of Arnould would have been used to position the bone plate during insertion of the cross screw. (EX2007, ¶¶43-45, 63-66). For example, Arnould describes the use of screw 2 and oblong hole 16 to "partially immobilize" the plate body 10 until the screw 2 is later "completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M." (EX1006, ¶¶31-33, 8).

Arnould's plate is not at risk for unwanted torqueing or spinning like Zahiri's guide plate because Arnould's plate is (1) contoured to the metatarsal and phalanx, with a leg designed to wrap around the phalangeal epiphysis, and (2) "partially immobilized" by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.*, ¶31). As such, a POSITA would understand that proper alignment and temporary fixation is obtained in Arnould ***without*** the need for "temporary guide pins used with pin holes" of Zahiri. (EX2005, ¶¶253-255; EX2007, ¶¶43-45, 63-66).

d. No Reasonable Expectation of Success

Petitioner fails to explain whether a POSITA would have had a reasonable expectation of success in making the combination of Arnould and Zahiri. Its conclusory statement that a POSITA would have looked to Zahiri because "bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades" is insufficient. (Pet., 64). As discussed above, the Federal Circuit requires a showing of reasonable expectation of success in making a combination for the purposes of demonstrating obviousness. *Stepan*, 868 F.3d at 1345-46 n. 1. This is especially so here, where a POSITA would have understood that fusing an MTP joint with Arnould's bone plate is fundamentally different than using Zahiri's device to guide the position of a lag screw across a proximal humeral fracture at a fixed angle. (EX2005, ¶¶256-258).

e. Petitioner Fails to Demonstrate a Motivation to Combine the Different Embodiments of Zahiri

As it did in Ground 2 with respect to the combination of Slater and Zahiri, Petitioner improperly relies on the different embodiments of Zahiri without providing any motivation to combine those embodiments and without explaining whether a POSITA would have had a reasonable expectation of success in making such combinations. (Pet., 71 (relying on Fig. 4 for the claimed "third hole"); *Id.*, 72 (relying on Fig. 8 for the claimed "second hole"); EX2005, ¶¶259-264). Petitioner

therefore fails to carry its burden in demonstrating obviousness. *Stepan*, 868 F.3d at 1345-46 n. 1.

For the reasons explained above, a POSITA would not have been motivated to combine Arnould with Zahiri. (EX2005¶¶235-264).

2. Arnould and Zahiri Do Not Render Obvious Independent Claims 1, 11, and 17

a. Claim 1

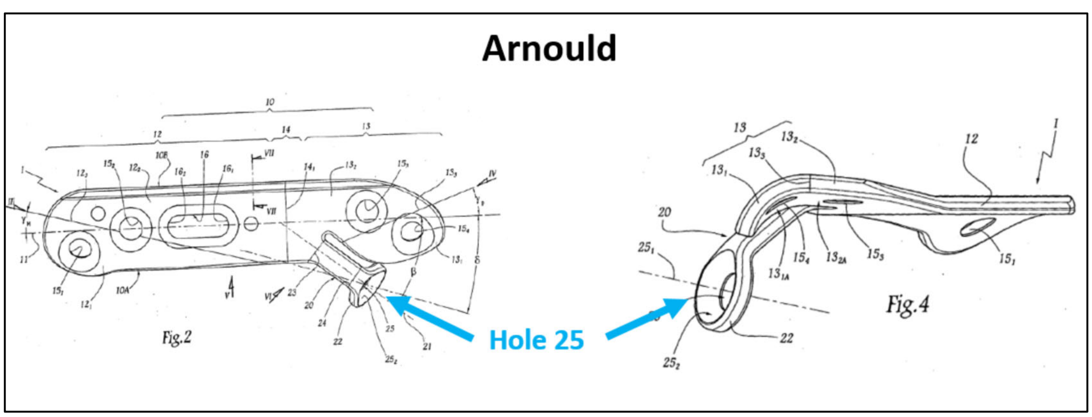
i. Claim Element [1d] "A Third Hole Located Between Said First Hole and Said Second Hole"

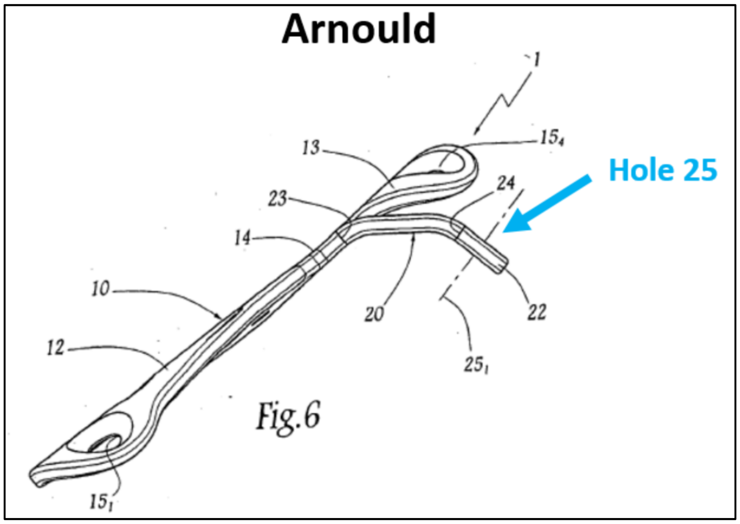
The Petition nowhere explains how Arnould allegedly discloses "a third hole located between said first hole and said second hole." (Pet., 69-70). Similarly, Mr. Sherman simply cites to Figure 2 of Arnould without any explanation or annotation. (EX1002, ¶264). It appears that Petitioner simply assumes that hole 25 of leg 20 of Arnould is "between said first hole and said second hole." (*Id.*). It is not.

As discussed *supra* in Section IV, the claim term "between" from independent claims 1, 11, and 17 means "at, into, or across the space separating two objects, places, or points." (EX2015). As shown below in Figure 1 of the '751 patent, use of the term "between," such as "a third hole located ***between*** said first hole and said second hole," refers to the third hole located in the space separating the first hole and the second hole.

According to Petitioner, "a POSITA would understand that hole 25 is a third hole that is offset at angle β with respect to the longitudinal axis of the plate." (*Id.*). But angle β is formed by the longitudinal direction 11 and longitudinal direction 21 of leg 20, not hole 25. (EX1006, ¶25; EX2005, ¶270-271). Similarly, while the trajectory of screw 30 may be angled, it does not follow that hole 25 is necessarily angled. (*Id.*). Rather, the size and shape of the screw head may permit the screw to be placed at different trajectories regardless of whether the hole is angled.

As shown below in Figures 2, 4, and 6, hole 25 is not an "angled hole" as claimed. Rather, hole 25 appears to have the same shape and geometry of holes 15_1, 15_2, 15_3, and 15_4, none of which are angled through the bone plate. (*Id.*, Figs. 2, 4, 6; EX2005, ¶272). Hole 25 includes "a concave surface which is substantially complementary to an associated surface delimited by this screw head." (EX1006, ¶27). Arnould does not state that hole 25 is itself angled relative to the longitudinal axis of the plate. (EX2005, ¶273).





(EX1006, Fig. 2, Fig. 4, Fig. 6). As such, Arnould does not disclose this claim element.

In apparent recognition that Arnould does not disclose an "angled" hole as claimed, Petitioner alleges that "[a] POSITA would also have looked to Zahiri for way to provide better compression across the joint because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture." (Pet., 70). As an initial matter, Petitioner does not explain how Zahiri allegedly provides "better compression across a joint" or how providing better compression is related to a hole being "angled relative to the longitudinal axis." As Mr. Sherman concedes, since Zahiri is not even directed to arthrodesis, Zahiri indisputably does not provide a way to provide better compression across a joint as Petitioner incorrectly contends. (EX1007, 2:16-19; EX2005, ¶¶274-275; EX2009, 134:14-19).

Petitioner's purported reason to combine, i.e., "because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture," is conclusory, deficient, and does not explain why a POSITA would have had a reasonable expectation of success in combining Zahiri with Arnould. *See Veterinary Orthopedic Implants*, IPR2019-01332, Paper 17 at 48-49. Contrary to Mr. Sherman's broad statement, a POSITA would have recognized that while ***some*** bone plates may be used for joint fusion and fracture fixation, this does not mean that ***every*** bone plate for fracture fixation necessarily can be interchanged with ***every*** bone plate for joint fusion. (EX2005, ¶258). Here, as explained above, Zahiri does not even disclose a bone plate. (*Id.*, ¶¶34, 76-82, 121-129, 237-238). As explained above, a POSITA would not be motivated to combine Zahiri's angled hole within a barrel with Arnould's thin MTP plate. (Section V.D.1.b).

Finally, Petitioner improperly relies on the different embodiments of Zahiri in attempting to arrive at the claimed limitation. As discussed above in Sections V.B.1.e and V.B.2.b.i, Petitioner relies on the multiple embodiments of Zahiri to meet the limitation for "said third hole is angled. (Pet., 71). Petitioner's analysis of this claim fails to acknowledge that Zahiri discloses multiple distinct embodiments, fails to provide a motivation or reason to combine the embodiments of Zahiri, and

fails to explain whether a POSITA would have had reasonable expectation of success in the resulting combination. *Stepan*, 868 F.3d at 1345-46 n. 1.

For the above reasons, Arnould and Zahiri do not render obvious claim 1. (EX2005, ¶¶265-275).

b. Claim 11

i. Claim Element [11d]

The Petition relies solely on Zahiri for claim element [11d], stating that "Arnould is silent regarding the dimensions of hole 25" and that "[a] POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings." (Pet., 78).

Petitioner states that "Zahiri discloses this claim element," citing to Section VII.D.2.b.v, Petitioner's earlier analysis of "[11d] a third hole" for Ground 2 based on **Slater and Zahiri**. (*Id.*, 78). Like its Ground 2 analysis, Petitioner (and Mr. Sherman) conclusorily state: "[l]ooking for a way to improve the integrity of the angled fixation screw of Arnould's bone plate, a POSITA would consider the disclosure of Zahiri to implement this improvement." (*Id.*; EX1002, ¶287). Petitioner does not explain ***why*** a POSITA would need to "improve the integrity of the angled fixation screw," ***why*** a POSITA would specifically look to Zahiri, and

whether a POSITA would have a reasonable expectation of success in making such combination. *TQ Delta*, 942 F.3d at 1359.

To the extent Petitioner's allegations can be understood in view of its confusing shorthand that does not align with its Claim Appendix, claim 11 must fail because Arnould does not disclose "a third hole and a fourth hole located between the first hole and the second hole." (Section V.D.2.a.i; EX2005, ¶277-278). Moreover, for the reasons discussed above in Section V.D.1.b and V.D.1.d-e, a POSITA would not have been motivated to combine the alleged "third hole and fourth hole" of Zahiri with Arnould.

ii. Claim Element [11h]

With respect to claim element [11h], Petitioner relies on the lag screw of Zahiri that perfectly mates with the strict geometry of barrel portion 38. (Pet., 79-80). As explained above in Section V.D.1.b, incorporating Zahiri's barrel portion into Arnould removes the ability to select multiple trajectories for the screw 30 of Arnould. A POSITA would understand that Zahiri's locking screw/lag screw arrangement, which is received by Zahiri's barrel portion, would not fit in the thin, pliable, metatarsophalangeal plate of Arnould. (EX2005, ¶¶279-284). As such, Arnould and Zahiri do not render obvious "a third fixation member configured to be

inserted ***through the third hole and fourth hole***." (Pet., 80; Section V.D.1.b and V.D.1.d-e).

Thus, Arnould and Zahiri do not render obvious claim 11.

iii. Claim Elements [11e] and [11i]

Petitioner relies on Zahiri for claim elements [11e] and [11i] (mislabeled in the Petition as [11k]) and claims that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of known temporary fixation members." (Pet., 78-79, 81-82). Petitioner is wrong.

As discussed above in Section V.D.1.a, a POSITA would not have been motivated to look at Zahiri's guide plate and barrel portion for use in certain proximal humeral fractures, as Zahiri is not analogous art to Arnould's bone plate for fusing an MTP joint. (EX2005, ¶¶34, 76-82, 237-238). Moreover, a POSITA would not have been motivated to look to Zahiri for disclosure of known temporary fixation members because Arnould discloses the use of screw 2 and oblong hole 16 to "partially immobilize" the bone plate, thereby eliminating the need to incorporate Zahiri's alleged "fifth hole" and "a temporary fixation member configured to be inserted ***through the fifth hole***." (*Id.*, ¶¶285-287; EX2007, ¶¶43-45, 63-66). As such, a POSITA would not have been motivated to include "the temporary fixation

members" of Zahiri "to improve Arnould's plate to guide the plate alignment." (EX2005, ¶¶285-287; EX2007, ¶¶43-45, 63-66; Pet., 79, 82).

Moreover, following Petitioner's cross reference leads to Petitioner's improper reliance on the different embodiments of Zahiri for Ground 2. (*Id*., 39, 79; Section V.B.2.b.i). Petitioner's analysis of these claim limitations also fails to explain why a POSITA would have had a reasonable expectation of success in making the alleged combination of Arnould and Zahiri. *Veterinary Orthopedic Implants, Inc.*, IPR2019-01332, Paper 17 at 48-49.

Thus, Arnould and Zahiri do not render obvious claim 11.

c. Claim 17

i. Claim Element [17d] "A Third Hole Located Between Said First Hole and Said Second Hole."

As discussed above with respect to Ground 2, Petitioner's analysis of Ground 4 as to independent claim 17 fails to comply with 35 U.S.C. § 312(a)(3). (Pet., 82-86). Petitioner's breakdown of claim elements bears no resemblance to its Claim Appendix. (*Compare Id*., 82-86 *with* 97).

To the extent Petitioner's allegations can be understood, and for the reasons discussed above with respect to claim 1 of Ground 4, Arnould does not disclose "a third hole located between said first hole and said second hole." (Section V.D.2.a.i;

EX2005, ¶¶288-289). Moreover, for the reasons already described, a POSITA would not have been motivated to combine Zahiri with Arnould. (Section V.D.1.b and Section V.D.1.d-e).

ii. Claim Element [17d] "Said Third Hole Being Angled Relative to Said Bone Plate"

For the reasons discussed above with respect to claim 1 of Ground 4, Arnould does not disclose "said third hole being angled relative to said bone plate." (Section V.D.2.a.i-ii; EX2005, ¶290). Moreover, because Petitioner fails to provide a motivation or reason to combine Zahiri with Arnould for this limitation, the Board should reject Petitioner's alleged combination of Arnould and Zahiri for claim 17.

iii. Claim Element [17e]

For claim element [17e], Petitioner provides a cross reference to a completely different claim limitation without reconciling the differences in claim language. (Pet., 85 ("[17i] [*sic*, [17e] [a pin hole located]" referring to Section VII.F.2.b.vi "[11e] [a fifth hole]" at 78)). Mr. Sherman does the same. (EX1002, ¶321). To the extent that Petitioner equates the "pin hole" of claim 17 with the "fifth hole" of claim 11, Petitioner's analysis is insufficient to demonstrate obviousness of claim 17 for

the same reasons set forth in SectionV.D.2.b.ii.[10] As discussed above in Section V.D.1.c-e, a POSITA would not be motivated to combine the temporary fixation techniques set forth in Zahiri because the pre-existing screw 2 would have been used with oblong hole 16 of Arnould to "partially immobilize" the bone plate, thereby eliminating the need to incorporate Zahiri's temporary fixation features. (EX2005, ¶¶291-295; EX2007, ¶¶43-45, 63-66; EX1006, ¶31). As such, a POSITA would not have been motivated to combine Zahiri with Arnould in arriving at claim 17.

Thus, Arnould and Zahiri do not render obvious claim 17.

3. Arnould and Zahiri Do Not Render Obvious Dependent Claims 2-3, 7-10, 12-16, and 18

Claims 2, 3, and 7-10 depend on claim 1, claims 12-16 depend on claim 11, and claim 18 depends on claim 17. Because Arnould and Zahiri do not render obvious claims 1, 11, and 17 of the '751 patent, Arnould and Zahiri do not render obvious claims 2, 3, 7-10, 12-16, or 18 either. (EX2005, ¶¶296-322).

a. Claims 9, 10, 15, 16, and 18

[10] The Petition provides an abbreviated heading for "[17i]" but the heading is nowhere located in the claim appendix. (Pet., 97).

For Ground 5, Petitioner's evidence does not, and cannot, support a motivation to combine Arnould, Zahiri, and Myerson.

The Petition relies solely on paragraphs 343 and 344 of the Sherman Declaration to supports its alleged basis for combining Arnould, Zahiri, and Myerson. (Pet., 90 (citing EX1002, ¶¶343, 344)). But paragraphs 343 and 344 of the Sherman Declaration are directed to the "MTP joint" and "locking screws or threaded holes." Claim 6 of the '751 patent is directed to the "tarsometatarsal joint" and does not recite limitations relating to locking screws or threaded holes. (EX1001, cl. 6; EX2005, ¶324). While Petitioner presumably erred by copying portions of the Sherman Declaration at paragraphs 247 and 248 of IPR2022-000487, Petitioner has waived any argument directed to combining Arnould, Zahiri, and Myerson. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286–87 (Fed. Cir. 2017) (finding that a Petitioner cannot "cure the petition's deficiencies in its subsequent briefing to the Board").

Moreover, the Board should reject Petitioner's alleged combination for claim 6 because Petitioner relies on hindsight to pick and choose certain claim elements from discrete pairs of references (*e.g.*, Arnould with Zahiri, Arnould with Myerson). (Pet., 90-91). 35 U.S.C. § 103 contemplates an analysis of the differences between the claimed invention and the prior art to determine whether the claimed invention

Myerson

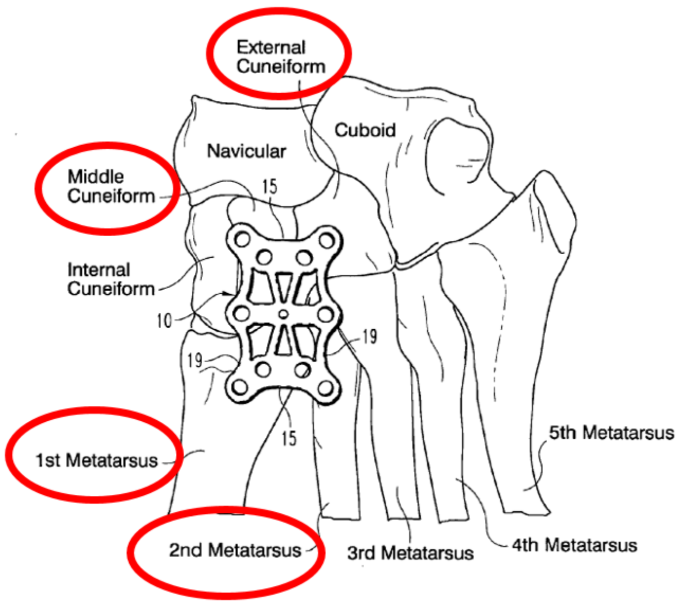


Fig. 1

(EX1010, Fig.1). Petitioner does not explain how Arnould's MTP plate would have been modified to span such bones. For example, Petitioner is silent as to how leg 20 would be positioned when attempting to fuse the tarsometatarsal joint. Indeed, the principles described in Arnould are specific to MTP joints and teach away from the modification of the plate for use with the TMT joint. (EX2005, ¶¶323-329, 83-85). As such, Arnould, Zahiri, and Myerson does not render obvious claim 6.

VI. CONCLUSION

Petitioner has failed to satisfy its burden in demonstrating that the Challenged Claims are invalid. The Board should find that the Challenged Claims are patentable.

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00488
U.S. PATENT NO. 10,993,751

PETITIONERS' REPLY IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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"between" their head and their feet. *Id.*, 153:1-12. While PO purports to rely upon the figures in the '751 Patent to support this construction (*id.*), the figures actually illustrate a plate that would not satisfy PO's proposal because, like a person's hand, the '751 Patent's cross-joint hole (green) is actually ***below*** the planar space between the first and second holes (blue):

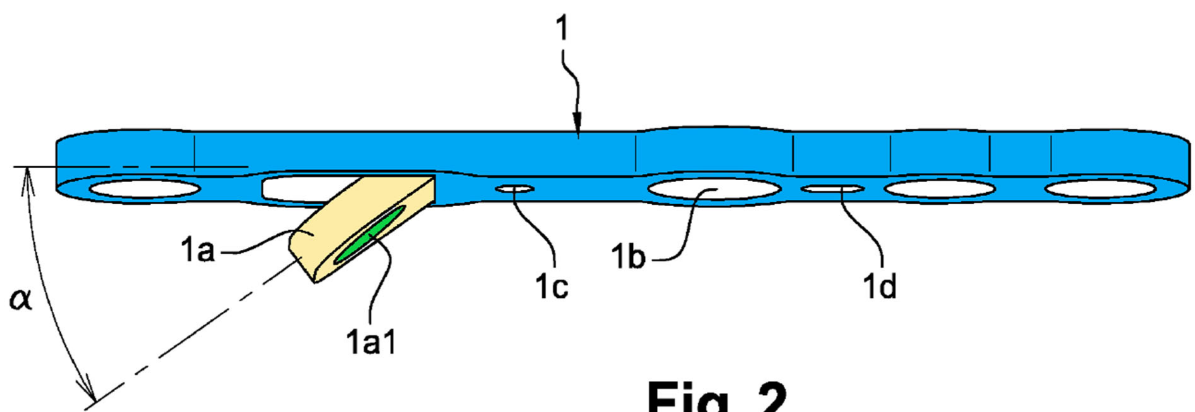


Fig. 2

Ex. 1001, Fig. 2.

PO's construction that would exclude the preferred embodiment cannot be accurate. *SynQor, Inc. v. Artesyn Tech., Inc.*, 709 F.3d 1365, 1378-79 (Fed. Cir. 2013).

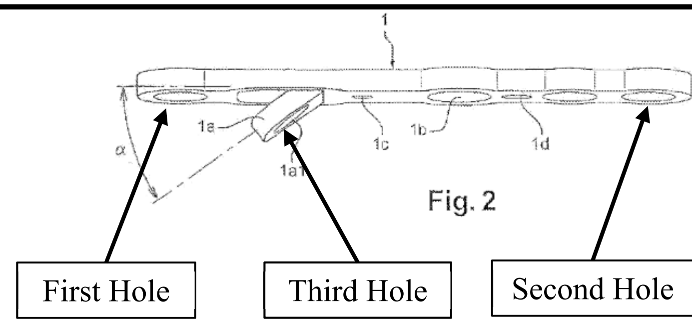
VI. GROUND 4: ARNOULD + ZAHIRI

A. Claim 1

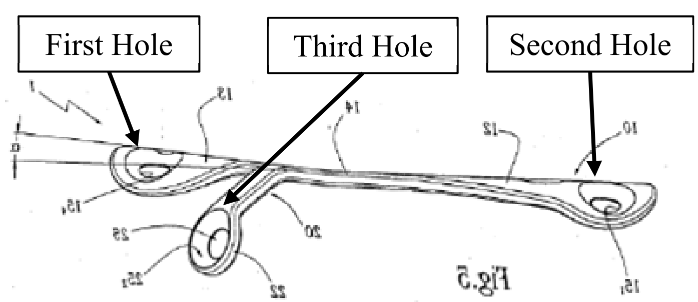
1. [1d]

PO's argument regarding Arnould's "third hole" turns on its improper view of "between," discussed above. In applying its construction to exclude the third hole of Arnould as being between the first and second holes, PO ignores the '751 Patent's only illustrated embodiment shows the third hole on a tab that, like leg 20 of Arnould, is "plunging downward":

'751 Patent



Arnould



Ex. 1001, Fig. 2 (annotated); Ex. 1006, Fig. 5 (reversed, annotated). In both figures, the third hole is between the first and second holes, even though both are below the main body of the plate.

PO's argument contradicts arguments it has made regarding Arnould in related IPRs. There, PO argued leg 20 is "part of the elongate spine," where "the 'elongate spine' is understood to include the first end [of the plate], the second end [of the plate], and the bridge disposed between." *See* Ex. 1023, 27-28. According to PO, the leg 20 hole is "disposed along the spine" of Arnould. *Id.* at 29. If the hole is part of and indeed disposed along the spine of the plate, then the third hole is also between the first and second end holes.

PO's argument that Arnould fails to disclose the third hole angled relative to the longitudinal axis also fails. The surface of Arnould's third hole, like the third hole in the '751 Patent is not in the same plane as the main body of the Arnould plate, but rather angled relative to it, just as the claim requires. PO strangely argues that hole 25 is not an "angled hole" because it has the same shape and geometry of the other holes shown on Arnould's plate. POR, 74. Yet, the '751 Patent illustrates a single angled hole on a tab below the surface of the bone plate that has the same shape and geometry of the other holes depicted. Moreover, PO seems to suggest the hole itself has to have some angular geometry, but the claim simply reads the "third hole is angled relative to the longitudinal axis" of the bone plate. Ex. 1001, cl. 1.

Arnould's third hole identified in the Petition meets this requirement without turning to the disclosure of Zahiri, rendering PO's combination challenges irrelevant. Nevertheless, a POSITA would be motivated to improve the integrity of hole 25 while still ensuring flexibility of the screw trajectory because of pliable leg 20. Ex. 1007, [0023]; *see also* Petition, 69-70 (surgeons able to modify angle δ relative to the longitudinal axis). In addition, "[a] POSITA would also have looked to Zahiri for a way to improve the integrity of the angled fixation screw," such as by having the screw 30 of Arnould fully seated. Petition, 76.

B. Claim 11

With respect to [11d] and [11h], PO focuses its argument on the propriety of the combination, rather than the sufficiency of the disclosure. As discussed above and in the Petition, Arnould alone teaches these elements to a POSITA, and PO's motivation arguments fail.

Turning to elements [11e] and [11k], PO argues it would be unreasonable to incorporate Zahiri's pin holes and temporary fixation members. But, this argument fails to recognize that Arnould itself discloses pin holes. Petition, 64. For additional details regarding these pin holes, a POSITA would be directed to Zahiri, as discussed above regarding the Slater combination. *See* Section IV.B.3; *see also* Petition, 65-66.

C. Claims 9, 10, 15-18

PO's arguments with respect to claims 9, 10, and 15-18 have been disposed of above in relation to claims 1 and 11.

VII. GROUND 5: ARNOULD + ZAHIRI + MYERSON

PO's argument focuses on an error in Mr. Sherman's declaration that somehow negates the express teachings of Myerson. *See* POR, 84. Mr. Sherman's statements specific to Ground 5 confirm he was referring to the disclosure of the tarsometatarsal joint in Myerson with respect to claim 6 and describe that a POSITA would understand how to apply Arnould to the TMT joint in view of Myerson's disclosure. *See, e.g.*, Ex. 1002, ¶¶345-347; *see also id.*, ¶¶244-256. This is especially clear given that the MTP joint is not discussed in Myerson.

Dated: February 17, 2023

Respectfully submitted by

K&L GATES LLP,

By: /Jason A. Engel/
Jason A. Engel
Reg. No. 51,654